HOUSE OF LORDS

SESSION 1999–2000
2nd REPORT

SELECT COMMITTEE ON
SCIENCE AND TECHNOLOGY

MEETING WITH HEALTH AND SCIENCE MINISTERS

REPORT WITH EVIDENCE

Ordered to be printed 7 December 1999

LONDON: THE STATIONERY OFFICE
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HL Paper 11

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CONTENTS

NOTES

The Human Genetics Advisory Commission was succeeded by the Human Genetics Commission on 1 January 2000.

Dr Poste retired from SmithKline Beecham on 31 December 1999.

Q in the text refers to a Question in the oral evidence.

SECOND REPORT

7 DECEMBER 1999

By the Select Committee appointed to consider Science and Technology.

ORDERED TO REPORT

MEETING WITH HEALTH AND SCIENCE MINISTERS

On 7 December 1999, we received oral evidence from John Denham MP, Minister of State for Health; Yvette Cooper MP, Minister for Public Health; and the Lord Sainsbury of Turville, Minister for Science and Innovation.

The witnesses answered questions on:

clinical academic careers—QQ 1–12;

directed cell culture[1]—QQ 13–30;

the possibility of an NHS-wide genetic database—QQ 31–38; and

the NHS research and development strategy—QQ 39–43.

The transcript of our exchanges is appended to this Report. Also appended are prior background memoranda on each of the three main topics from the Department of Health and from others.

We have had a long-standing interest in the development of clinical academic careers. On that matter, this Report may therefore be read as a continuation of the Committee's Reports from 1995 on *Medical Research and the NHS Reforms*[2] and from 1997 on *Clinical Academic Careers*[3]. In the case of the NHS research and development strategy, our interest goes back to our 1988 Report *Priorities in Medical Research*[4].

Prospects for directed cell culture and a possible NHS-wide genetic database are much newer issues. This was the first occasion on which we have considered these potentially exciting but complex topics.

[1] This covers a variety of procedures and techniques. As the subject first emerged from the possible application of human cloning techniques for therapeutic purposes, it is often referred to as "therapeutic cloning" or "cell nucleus replacement". More recently, the prospect has emerged of achieving similar therapeutic ends through the culture of pluripotential stem cells. We have adopted the term "directed cell culture" to indicate this larger field of what might also be called tissue engineering.

[2] 3rd Report 1994-95, HL Paper 12.

[3] 3rd Report 1997-98, HL Paper 47.

[4] 3rd Report 1987-88, HL Paper 54.

APPENDIX

Members of the Select Committee

Lord Haskel
Lord Howie of Troon
Lord Jenkin of Roding
Lord McColl of Dulwich
Lord Methuen
Lord Oxburgh
Lord Patel
Lord Perry of Walton
Baroness Platt of Writtle
Lord Quirk
Lord Rea
Lord Tombs
Lord Wade of Chorlton
Lord Walton of Detchant
Baroness Warwick of Undercliffe
Baroness Wilcox
Lord Winston (Chairman)

WRITTEN EVIDENCE

Memorandum by the Department of Health

CLINICAL ACADEMIC CAREERS

Background

1. The Science and Technology Select Committee expressed concerns about the position of clinical academics in its 1995 report *Medical Research and the NHS Reforms.* In response, the Committee of Vice Chancellors and Principals (CVCP) commissioned the Task Force on Clinical Academic Careers chaired by Sir Rex Richards. The Richards Report, which the CVCP published in July 1997, described the pressures on clinical academics and made recommendations on how these pressures might be alleviated.

2. The Select Committee interviewed Sir Rex Richards and members of his team in November 1997 and subsequently published a short report *Clinical Academic Careers.* In this report the Committee welcomed the initiative by the NHS Executive and the Higher Education Funding Council for England (HEFCE) to establish two joint Department of Health (DH)/HEFCE task groups. This initiative was a positive response to concerns about the outcome of the 1996 Research Assessment Exercise (RAE) in relation to clinical health services research and the interrelationship between research, teaching and patient care. The Committee also welcomed, and appended to the report, Sir Alan Langlands' letter of 24 November 1997 which summarised a number of other developments which had taken place since Sir Rex Richards began his inquiry. Further progress continues to be made as set out below.

Increasing Medical School Intakes

3. The Richards Report recommended that "any increase in the target numbers for medical student admissions must be accompanied by a corresponding increase in the numbers of clinical academic staff and the facilities to accommodate them". In July 1998, the Government accepted the recommendation of the third Report of the Medical Workforce Standing Advisory Committee (MWSAC) that the intake of students to medical schools in the United Kingdom should be increased by about 1,000 places per annum (about 20 per cent) to about 6,000. The need to accommodate a significant increase in the numbers of clinical academics nationally was one of the factors reflected in the planned phasing of the increase over the period 2005.

4. Most of the additional medical student places will be in England, and the HEFCE was advised in the allocation of places by a Joint Implementation Group (JIG) co-chaired by the Permanent Secretary of the Department of Health and the Chief Executive of the HEFCE. The increase in students in Wales was 35 in the only Welsh undergraduate medical institution—the University of Wales College of Medicine—and there may be more following consideration by the National Assembly for Wales. Northern Ireland and Scotland did not plan any significant increase. Scotland will continue to produce more doctors than its proportion of the UK population would indicate.

5. The JIG required all bidders to satisfy it on the availability of suitable clinical academic staff. The JIG bidding form, which was sent to all Universities and NHS Chief Executives in England on 8 January 1999, required all bidders to comment specifically on:

> ". . . the numbers of clinical academic staff, currently engaged, additional recruitment implied by the proposal, and anticipated ease of recruitment. . . ."

6. The need to ensure effective academic support was reflected in the linking of new centres of medical education to existing medical schools. Three have been announced so far:

- Keele (Manchester).
- Warwick (Leicester).
- Durham, Stockton Campus (Newcastle).

Pay Parity with NHS Colleagues

7. The Richards Report referred to clinical academics' longstanding concern about pay parity with NHS colleagues; progress on this issue was reported in Sir Alan Langlands' letter of 24 November 1997.

8. Pay parity has been maintained between clinical academics and their NHS colleagues. In order to meet the terms of the new DfEE condition of grant in relation to clinical academic pay announced in November 1996, the HEFCE wrote on 14 March 1997 to all institutions which had received Council funding for teaching and/or research in clinical medical and dental subjects. The letter said that their recurrent grant payment for March 1997 would include an allocation to meet additional costs arising from the Government's award to clinicians following the Review Body recommendations, for the period April 1996 to July 1997. This took into account HEFCE's most recent estimates of clinical academic staff costs to the sector, and the differential

between the clinical pay award over the period and that for other academic staff. Further funds were allocated for the academic years 1997–98 and 1998–99.

9. In Scotland, the SHEFC concluded that further resources were not required for 1997–98 because of an additional £15 million allocated to teaching this year and because the differential would be small enough to be easily absorbed by the institutes. Parity has thus been maintained for 1997–98. The then Scottish Office Education and Industry Department nevertheless advised that the SHEFC needs to consider extra funding for that part of the 1998–99 financial year which falls within the 1997–98 academic year and also to recognise the ongoing requirement for parity with clinical academics. For 1998–99 (and 1999–2000) a condition of grant was applied and the SHEFC has made a specific allocation to institutions to maintain parity. These will be reviewed and adjustments made as necessary from within the SHEFC's resources. The Scottish Executive welcomes the inclusion of clinical academics in the Review Body's consideration.

10. In Wales as in England it was agreed that pay parity between clinical academics and their NHS colleagues should be maintained. The Secretary of State's letter of 15 December 1998 to the HEFCW stated that it was a continuing condition of grant funding of the HEFCW that the Council enables institutions to meet any additional costs for medical schools from the Government's award to clinicians following the Doctors' and Dentists' Review Body recommendations.

Access to Distinction Awards

11. The Richards Report recommended that the recognition of academic distinction in the award of discretionary points be kept under annual review. The report also expressed concern about the absence of an equivalent mechanism for rewarding academic GPs. As part of the consultant contract negotiations between the UK Health Departments and the BMA, a review of the discretionary points and distinction awards schemes is being undertaken.

Higher Specialist Training

12. As the Select Committee is aware, in response to concerns over the implementation of the Calman reforms to higher specialist training and their effects on clinical academic medicine, the Department of Health (on behalf of the four UK Health Departments) issued an Academic and Research Medicine supplement to the *Guide to Specialist Registrar Training* to explain the flexibilities and opportunities which exist under the new training arrangements. This was incorporated into the revised version of the Guide which was published in February 1988.

Academic and Research Sub-group of the Advisory Group on Medical Education Training and Staffing (AGMETS)

13. The Academic and Research sub-group of AGMETS, which was pivotal in producing the supplement to the *Guide to Specialist Registrar Training,* continues to provide a forum for the academic and research community to discuss matters of mutual concern with senior DH officials. The sub-group meets approximately twice-yearly under the chairmanship of Professor John Temple. The current work programme includes a joint JCC/DH Symposium on Careers in Academic Medicine which is being held in Birmingham on 5 October 1999. The symposium aims to publicise the action which has been taken to address the disincentives to academic careers, to disseminate examples of good practice and to identify solutions for outstanding problems. Health Department representatives for Wales, Scotland and Northern Ireland will also be involved.

Dental Education

14. Following the request from the Council of Deans of Dental Schools (CDDS) and the CVCP and some discussion at meetings of the Steering Group on Undergraduate Medical and Dental Education and Research (SGUMDER), the Dental Schools and Dental Hospitals Priorities Group was set up in June 1998 under the chairmanship of the Chief Dental Officer for England. The membership is representative of those bodies with an interest in Dental Schools and Dental Hospitals in England. The Group's remit is to consider the implications for undergraduate and postgraduate education and training of England's current and future need for dentists, to determine the priorities for dental schools and dental hospitals in meeting that need, and to make recommendations to appropriate bodies. The Group is expected to report its findings to SGUMDER and other appropriate fora in autumn 1999. A separate group is considering the position in Scotland.

Research Assessment Exercise

15. The Richards Report drew attention to the impact of the 1996 RAE. In England, the first of the two joint DH/HEFCE task groups, which were announced by Sir Alan Langlands and Sir Brian Fender in their letter of 26 June 1997, was asked to consider how health-related research should be handled in the next RAE. The Task Group was jointly chaired by DH and HEFCE officials and the membership included

representatives of NHS R&D and academic advisers to the HEFCE. The Group has considered the units of assessment to be used in the RAE, the criteria for assessment, assessment panel membership and whether special initiatives might be taken to encourage investment in developing areas such as health services research and primary care.

16. The Task Group issued a consultation document in August 1998 and in the light of the response made a number of specific proposals on how the RAE might best deal with DH and NHS strategic issues in respect of health services research. For the next RAE in 2001: sub-panels will cover strategic interest areas; and ratings for subject areas agreed by each of the sub-panels will be published.

17. The final report from Task Group I has been submitted to HEFCE and DH.

18. A current issue for the employment of clinical academics is the pressure on universities to substitute research academic posts for clinical academic posts to reduce their costs and to benefit their RAE position. The potential consequences for teaching and clincial care are recognised as an issue in the Richards' Report and for DH/HEFCE Task Group II. In Scotland this has led to the funding of clinical lectureships through the Scottish Council for Postgraduate Medical and Dental Education in order to ensure that there is a sufficient input of medically qualified clinical experience into the teaching process.

Improving NHS/university liaison: JMAC report *Good Practice in NHS/academic links*

19. Sir Alan Langlands' letter of 24 November 1997 informed the Select Committee of a joint initiative with HEFCE to identify and disseminate examples of good NHS/university partnership at local level. In 1998, the HEFC's Joint Medical Advisory Committee (JMAC) commissioned the University of Manchester's Health Services Management Unit to undertake a study of good practice in NHS/university relations. The study was concerned with the ways in which the NHS and universities are dealing with:

— competing pressures on staff time for teaching, research and patient care;

— curriculum change and changes in the pattern of clinical placements; and

— issues arising from the implementation of the Culyer Report on supporting research and development in the NHS.

20. The study focused on the development of good practice in five study sites (Aberdeen, Cardiff, King's College London, Liverpool and Sheffield) but also gathered examples from other locations.

21. The report *Good practice in NHS/academic links* was published in March 1999 and has been distributed to heads of UK higher education institutions, heads of UK medical and dental schools and chief executives of NHS trusts, health authorities and health boards.

Improving NHS/university liaison: Nuffield Trust work on putting SGUMDER's Ten Key Principles into practice

22. The Richards Report recommended that "more work should be done to explore the concept of the University Hospital NHS Trust". Following some discussion of the Richards Report at SGUMDER and other fora, Sir Alan Langlands met the Chairman of CVCP's Medical Committee and the Chairman of the Council of Heads of Medical Schools to discuss their concerns about relationships between medical schools and NHS trusts and to explore how these might best be taken forward.

23. It was agreed that new structures and radical solutions should be avoided but that there would be benefit in improving collaboration and joint management processes in line with SGUMDER's Ten Key Principles. It was agreed to invite the Nuffield Trust to organise and host a small seminar of key players to discuss the development of ground rules to operationalise the Ten Key Principles at local level. The Nuffield seminar was held in November 1998. To inform the discussion, the Nuffield Trust carried out a survey of medical school deans and teaching hospital chief executives on the interface between medical schools and NHS trusts. The survey results, which were circulated with the JMAC report on *Good Practice in NHS/academic links,* confirmed that there is scope for improvement in many parts of the country but also identified some positive initiatives.

24. The November 1998 Nuffield seminar brought together a number of chief executives of university teaching hospitals, heads of medical schools, and other key players including the chief executives of the NHS Executive and of the HEFCE, to address the results of the survey and address the interface between the NHS and university sectors. It was agreed to form a smaller working group with the aim of considering a joint strategic appoach and producing guidance for its translation into local relationships. The November 1998 group will reconvene in October 1999 to consider the working group's report.

IMPROVING NHS/UNIVERSITY LINKS: DH/HEFCE TASK GROUP II

25. The second of the two DH/HEFCE task groups was set up, under the chairmanship of Professor Alasdair Breckenridge, to examine how best to take account of the interdependency between research, teaching and patient care in the funding of university medical schools in England. In particular, the Group's terms of reference are to:

— suggest what practical arrangements might be put in place by the HEFCE and the DH to anticipate and consider the potential impact of their funding decisions on university medical and dental schools and NHS service providers; and

— consider what practical steps universities and NHS employers might agree locally to help reconcile the competing pressures on clinical academics in delivering research, education and patient care.

26. The Task Group's report was submitted to Sir Alan Langlands and Sir Brian Fender in September 1999.

CONCLUSION

27. The Government recognise the importance of academic and research medicine and has taken note of the findings of the Richards Report. A considerable programme of work is underway to strengthen the partnership between the NHS and the higher education sector and address many of the issues which were highlighted in the Report. The Government are committed to an approach which takes full account of the key role of universities and of academic medicine in delivering the NHS of the future, and will continue to work with all the stakeholders to ensure that further progress is made in removing disincentives to a clinical academic career.

October 1999

Memorandum by the Academy of Medical Sciences

THREATS TO CLINICAL ACADEMIC CAREERS—SOME PROPOSED SOLUTIONS

BACKGROUND

1. The 1995 report of the House of Lords Select Committee on *Medical Research and the NHS Reforms* first drew attention to the problems developing in Clinical Academic medicine. It concluded that "the disincentives to an academic medical career are now so great as to warrant an immediate enquiry in their own right". The Government did not act on this recommendation but the Committee of Vice-chancellors and Principals (CVCP) did, by commissioning an independent task force to address the problems highlighted in the Select Committee report. Sir Rex Richards chaired the task force which reported in July 1997. After hearing evidence from Sir Rex and members of the task force in November 1997, the Select Committee reported that "we are persuaded more than ever that there is a genuine threat to academic medicine in the UK and therefore to health care as a whole". The Committee has recently expressed its continuing concern about the state of clinical academic medicine in the UK, and the issues covered in the Richards report.

2. This then was the position when the Academy of Medical Sciences was established in 1998; it now has 450 fellows drawn from all branches of academic medicine and medical science. The wide expertise of the fellows enables the Academy to represent authoritatively the interests of academic medicine across traditional clinical and scientific boundaries. A major concern for the Academy is the overall health and vitality of the clinical academic profession which, it believes, is critical to the advancement of both biomedical research and the practice of clinical medicine. It is conscious (and proud) of the current high reputation of the UK in this field but aware of how easily this position could be lost. Whilst aware of the wide ranging recommendations put forward in the Richards Report, the Academy considered that the most crucial issues were those affecting the clinical and research training of aspiring clinical academics. This is because there is still widespread concern that the recruitment of young, talented, research-minded clinicians into UK academic medicine is insufficient to maintain the current impetus and standard of medical research in the UK and the translation of this into improved patient care. In order to stimulate action to sustain the clinical academic workforce in specialist medicine and to establish it in generalist medicine, a Working Party was established.

The Working Party

3. The Academy of Medical Sciences Working Party on Career Structure and Prospects for Clinical Scientists was constituted under the chairmanship of Professor John Savill and assigned two main tasks:

(1) "to assess any barriers to academic training associated with recent changes in clinical career structure."

(2) "to develop constructive suggestions for developing career pathways for trainees in academic medicine."

4. The Working Party first met on 7 April. It is currently exploring a number of options and consulting some of the key organisations and individuals involved in policy-making in this area (eg the MRC, the Wellcome Trust, the Association of Medical Research Charities (AMRC), the Chief Medical Officer, the Director of Research and Development for the NHS and the Academy of Medical Royal Colleges). It plans to submit its final report by the end of the year.

Summary of findings to date

A. In relation to hospital specialist practice

5. The Working Party believes that (i) inadvertently inflexible implementation of Specialist Registrar (SpR) clinical training and (ii) changing perceptions of the role and value of clinical lectureships to universities driven by the Research Assessment Exercise are foremost among many factors contributing to strong disincentives for young clinicians contemplating a career in academic medicine in the hospital specialities. These disincentives are seen to be:

(a) Lack of a clear career structure in clinical academic medicine with resulting uncertainties in the prospects of ultimately obtaining a tenured senior post. This contrasts strongly with the clear career structure for a specialist registrar (SpR) with a National Training Number (NTN) who, typically, is qualified for an NHS consultant post after five years of training leading to a certificate of completion of specialist training (CCST).

(b) Lack of the flexibility in clinical and research training needed to encourage the development of individuals who are not only competitive in research but also able to undertake broad-based practice in the clinical front line and thereby serve as role models to promote further recruitment into academic medicines. Lack of flexibility is a particular problem for women and others with domestic commitments.

(c) Inappropriate pressure to start intensive research training early in the clinical career track, not because it is judged to be the optimal time, but because trainees in the Senior House Officer (SHO) grade believe that resulting publications and theses will improve the chances of gaining entry to an SpR programme and hence acquire the "grail-like" NTN essential for progress.

(d) The prolonged time taken to achieve "registrable" status in both the clinical and research aspects of training to enable a senior tenured post to be obtained.

B. In relation to general practice

6. The working party recognises that for general practice, the main issue is how to support and encourage research excellence in a young, emerging academic discipline, rather than how to maintain specialist academic excellence in the face of resource constraint and organisational change. Although training in general practice is different in structure to that in hospital specialities, similar disincentives also face the aspiring academic general practitioner:

(a) Lack of a clear career structure is also a strong disincentive to the young generalist. Not only is there a lack of appropriately resourced research environments in which to train but there is also continued difficulty in recruiting high class senior academic staff in general practice. In part, this reflects the status of full time university clinical academics in general practice, which is usually percieved as inferior to that of academic specialist colleagues, a problem compounded by current ineligibility for merit awards.

(b) The lack of flexibility in academic general practice derives particularly from difficulties in retaining principal status while pursuing an academic career. The apparent lack of support from the Medical Practices Committee exacerbates this situation.

Summary of recommendations

7. The Working Party appreciates the very different requirements for optimal training in research and clinical practice in the different specialities (compare for example, public health, paediatrics, neurosurgery or pathology) and in general practice. It considered carefully whether these could usefully be grouped into pure and applied research disciplines, but concluded that a flexible generic scheme was preferable to more specialised schemes. The Working Party is close to consensus on the following proposals but a final report is not anticipated until December 1999:

(1) *A "two stage" career track*

A "two stage" career track in clinical academic medicine should be adopted in as many hospital-based specialities as is practicable and considered also as a model for development of academic general practice (The Working Party is aware that the Royal College of Physicians of London has put forward a similar scheme for discussion):

(a) *A pluripotential first "doctoral" phase of about five years*

Individuals awarded prestigious full-time research training fellowships (ideally for 3 years) funded by the MRC, the Wellcome Trust or other AMRC approved medical research charities, or the NHS, should automatically be entitled to up to two years SpR training and an NTN. This would enhance the attractiveness of research training to the young whilst providing the safety net of straightforward transition to a conventional NHS career if trainees decided not to pursue an academic career and progress to—

(b) *A second "clinician scientist" pase of about five years*

Our key proposal is the establishment of a new centrally managed training grade dedicated to those committed to a clinical academic career, which will effectively offer the scrutiny of a "tenure track" post to trainees of the highest quality. This clinician scientist grade would be entered by obtaining an approved competitive intermediate (ie post-doctoral) MRC/research charity/NHS research fellowship or a university-funded clinician scientist post; either should provide a flexible combination of post-doctoral research training (much of this full-time), completion of clinical training leading to a CCST and carefully circumscribed opportunities to participate in clinical teaching.

(2) *Providing flexibility and security for our very best trainees*

Although mechanisms are currently available to deliver the career track outlined above, their flexibility is often found (or perceived) to be inadequate, especially in the second clinician scientist phase. Greater flexibility could, we think, achieved by provision for second phase trainees of prospective *ad hominem* clinical training programmes to allow optimum intermixing of clinical and research training and, for doctors with domestic commitments, periods of part-time working. Such flexibility could be achieved most easily by each Royal College setting up an academic training committee which, in consultation with appropriate specialist advisory committees would assume responsibility for training in the clinician scientist phase. This new scheme would require a small dedicated pool of clinician scientist NTNs to support trainees of such high quality that they would effectively be on a "tenure track" for senior academic positions. Since there are currently around five MRC/AMRC/NHS clinician scientists appointed each year, and because we anticipate that most medical schools will wish to establish one such post per year in anticipation of a senior retirement or to support plans to develop research excellence, we propose that around 50 dedicated "clinician scientist" NTNs would be needed per year.

(3) *Retention of clinical lectureships as a "bridge" to academic medicine*

We view the proposed clinician scientist grade as an attractive addition to the range of career opportunities available to academically-minded young doctors and a means by which to foster future leaders in clinical research. However, upon completion of the first phase some trainees will still be uncertain as to whether they wish to commit themselves to a research-led clinical academic career. Others may wish to develop a major interest in teaching, which the Working Party values very highly. Finally, in some specialities there are currently very few individuals with the training track record necessary to compete successfully for clinician scientist positions. In all these instances existing clinical lectureships recognised for honorary SpR training offer an important career opportunity and should be retained; immediate and wholesale conversion of clinical lectureships to clinician scientist posts is not our intention and could impair flexibility.

(4) *Competency-based assessment of clinical training*

We applaud the moves now being made by various bodies to investigate competency-based assessment of fitness to qualify for specialist registration, rather than measures based on time served, numbers of procedures undertaken and formal examinations passed. We are aware of the difficulties and dangers of moving in this direction but it could undoubtedly help to introduce more flexibility into academic programmes.

(5) *Academic flexibility SpR posts to provide early specialist training*

Urgent action is also needed to encourage more young clinicians to seek a first research training fellowship (RTF) and enter the "doctoral" phase, especially in specialities with limited academic activity or a "blocked" SpR grade. Consideration should be given to providing postgraduate deans with a limited pool of "academic flexibility" SpR salaries capable of supporting up to two years', "up front" SpR training before starting research training. This incentive scheme would, we estimate require a total of 100 SpR salaries each with a NTN. The Academy is well aware of the reluctance of the responsible authorities to create "extra" NTNs but the number required to create the flexibility we seek would be small but vital if we are to maintain a credible R&D function in the NHS. Current manpower planning is not a precise art and it is likely that such numbers would be within the margins of error (noise) of the present system.

(6) *Building academic general practice*

Further resourcing and development of relevant research training environments for clinical scientists in general practice are urgently needed. The lack of flexibility in the early years of general practice would benefit from funding of protected time to prepare research training fellowship applications at this stage while retaining principal status. The status of clinical academics in general practice should be brought fully into line with that of their colleagues in other clinical disciplines.

Conclusion and key points for action

8. Recruitment to Academic Medicine is at a crossroads. With some relatively simple changes, largely involving more flexibility in training programmes and assessment procedures, and redeployment of existing funding, we believe that academic medicine can be made more attractive to some of the best young doctors who are trying to decide which career path to follow. Failure to achieve this will have dire consequences, so we look for support and action from the relevant Government departments to:

— Support establishment of a new tenure track grade for clinical scientists who hold a research degree, are keen to complete clinical training and committed to a career in academic medicine. This would require a dedicated pool of about 50 NTNs per year and special recognition from the Royal Colleges. It should require little additional salary funding since, in addition to existing fellowships funded by the MRC, the Wellcome Trust and other AMRC charities, some posts could be created by upgrading existing clinical lectureships in universities keen to improve their clinical research status or anticipate a senior vacancy. However the Academy is keen to see the establishment of "portable" clinician scientist salaries in order to facilitate exploitation of training opportunities in the UK.

— Provide up to 100 protected "academic flexibility" SpR posts with NTN status for up to two years to enhance the attractiveness of research training by facilitating "upfront" clinical training for appropriate SHO "high flyers" prior to starting a research training fellowship. Funding for these posts might be obtained centrally from the R&D levy to acknowledge the importance to the R&D function of the NHS of maintaining clinical academic strength.

— Recognise that additional funding will be required to strengthen academic general practice and some of the "shortage" disciplines in secondary care. These funds will be required not only to support research training and the infrastructures needed in a "well-found" environment suitable for such training, but also to address the differences in salary once a permanent career post is obtained.

November 1999

Memorandum by the Department of Health

THERAPEUTIC CLONING

Introduction

1. The Department of Health welcomes this opportunity to assist the Science and Technology Committee in its consideration of therapeutic cloning.

The Human Fertilisation and Embryology Authority and Human Genetics Advisory Commission report

2. The HFEA/HGAC report *Cloning Issues in Reproduction, Science and Medicine* was published in December 1998. In making its recommendations the report distinguished between human reproductive cloning (ie designed to lead to the implantation of an embryo in a woman and the birth of a cloned human being) and research involving cell nuclear replacement or "therapeutic cloning".

3. On therapeutic cloning the HFEA/HGAC indicated that they saw potential benefits from research involving cell nuclear replacement order to develop treatments for:

(i) mitochondrial disorders; and

(ii) diseased or damaged tissues or organs.

4. The purposes for which the HFEA may currently authorise research involving human embryos are set out in the Human Fertilisation and Embyology Act 1990 (see Annex A.) Further purposes maybe specified in affirmative regulations. The HFEA/HGAC report invited the Government to consider such regulations to allow research on embryos for the two purposes they had identified.

The Government Response

5. The Government Response published in June 1999 also indicated that before deciding whether to make regulations to allow further research purposes the Government wished to take additional views on the potential benefits of the additional purposes suggested; whether there are alternative approaches which might offer the same benefits and whether there are additional or different research purposes which the technology might point to.

6. In making its response the Government took account of the fact that Parliament, on a free vote, has determined that research on embryos should be permitted under carefully controlled circumstances. However it also recognised that, as reflected in the HFEA/HGAC public consultation which preceded their report, there are a number of people who are opposed to such research under any circumstances. The Government therefore felt it was important to investigate further the suggested potential health benefits of research involving human nuclear replacement before deciding whether expanding the research purposes for which human embryos may be created or used is justified.

Additional research purposes

7. The HFEA/HGAC report notes that in the weeks immediately before the report was issued there had been reports of significnt developments in research in the US involving stem cells, of which the HFEA/HGAC had not been able to take full account. This research involved taking stem cells from early fetuses as well as embryos and had succeeded in establishing stable cell cultures.

8. This research appears to open up the possibility of therapeutic purposes beyond those specified by the HFEA/HGAC (at paragraph 5.10 of their report) such as treatment of leukaemia; use in gene therapy; and use as a tool in drug development for new treatments in a wide range of inherited and somatic disorders. In deciding whether or not to expand the permitted research uses of embryos the Government would wish to take account of the implications of this most recent research and the additional research and therapeutic possibilities it might suggest, over and above those outlined in the HFEA/HGAC report.

Alternatives to embryo research

9. The research referred to at paragraph seven also raises the question as to whether embryos created *in vitro* will or should be the main or preferred source of stem cells. Significant research is underway in the UK and elsewhere using stem cells and other pluripotent cells obtained from blood, cord blood and fetal tissue. Both ethical and practical considerations (including the scarcity of embryos and eggs for IVF treatment or research purposes) suggest that these alternatives merit serious consideration.

CMO Expert Group

10. In the light of the considerations outlined above, the Government Response announced the intention to establish an *ad hoc* Expert Advisory Group, chaired by the Chief Medical Officer on the need for, anticipated benefits and risks of, and alternatives, to the use of human embryos in research for the additional purposes suggested by the HFEA/HGAC Report. The membership and terms of reference of this group were announced on 18 August (press release at Annex B). At the same time, the CMO wrote to those who responded to the HFEA/HGAC's consultation and a range of additional experts working in relevant fields worldwide seeking their views on the following questions:

- what are the current areas of research in therapeutic cloning including stem cell studies, and which are the most important?
- what are the areas of human health in which the use of therapeutic cloning techniques is most likely to provide benefits?
- how close are we to being able to replicate animal work in humans?
- what are the technical problems which might arise?
- are you aware of any safety issues?
- are there alternatives to research on human embryos, created *in vitro*, to achieve the same ends? If so, is it likely that they will be available within the next five years?
- what are the ethical and social implications of such research and its potential therapeutic application?
- what would be the likely future consequences of the development of therapeutic cloning technology for health care provision?

11. The responses, which have been requested by the end of October, will help inform the Group's conclusions. The Government expects to receive the Expert Advisory Group's advice early in the New Year.

November 1999

Annex A

THE LEGAL POSITION

The Human Fertilisation and Embryology Act 1990 (Schedule 2 paragraph 3(2)) currently permits the Human Fertilisation and Embryology Authority to authorise research involving human embryos for the following purposes:

(a) promoting advance in the treatment of infertility;

(b) increasing knowledge about the causes of congenital disease;

(c) increasing knowledge about the causes of miscarriages;

(d) developing more effective techniques of contraception; and

(e) developing methods of detecting the presence of gene or chromosome abnormalities in embryos before implantation;

subject to the HFEA being satisfied that any proposed use of embryos is necessary for the purposes of the research and that the embryo is not kept or used beyond 14 days. The Act provides for further research purposes to be added subject to an affirmative resolution of both Houses.

Annex B

Department of Health Press Notice (Wednesday 18 August 1999)

MEMBERSHIP OF CHIEF MEDICAL OFFICER'S GROUP ON THERAPEUTIC CLONING ANNOUNCED

Professor Liam Donaldson, the Chief Medical Officer, today announced the membership and terms of reference of the group on therepeutic cloning. He will chair the group, which has been set up by the Government to consider the pros and cons of therapeutic cloning.

The Government announced its intention to set up an expert group to examine the potential benefits, risks and alternatives to therapeutic cloning research in its response to the joint report from the Human Fertilisation and Embryology Authority and Human Genetics Advisory Commission, Cloning Issues in Reproduction, Science and Medicine.

The terms of reference of the new group are:

— to establish the extent to which there is a current research focus on therapeutic cloning including stem cell studies, when developments are likely to arise and where they could lead;

— to asses the anticipated benefits of such research; the potential risk; and any alternative approaches that might be pursued to achieve the same benefits;

— in the light of the assessed benefits, risks and alternative to consider whether there are any ethical and social implications beyond those addressed by the HFEA/HGAC Report, *Cloning Issues in Reproduction, Science and Medicine;*

— to advise whether regulations need to be made under the Human Fertilisation and Embryology Act 1990 to extend the purposes for which the Human Fertilisation and Embryology Authority may issue licences for research involving human embryos; and

— to advise on whether any additional regulation of the use of embryonic cell lines (such as stem cells) is required.

The membership is:

Professor Liam Donaldson, Chief Medical Officer, (chair);

Professor David Baird, MRC Clinical Research Professor, Centre for Reproductive Biology, University of Edinburgh;

Professor WF Blakemore, Department of Clinical Veterinary Medicine, University of Cambridge;

Professor John Burn, Regional Genetics Services, Newcastle upon Tyne;

Professor Alastair Campbell, Professor of Ethics in Medicine, University of Bristol;

Professor Dian Donnai, CMOs consultant adviser in Genetics, Regional Genetics Services, Manchester;

Professor Martin Evans, Director and Professor of Mammalian Genetics, Cardiff University;

Professor Brian Heap, Master of St Edmunds College, Cambridge;

Professor David Linch, Department of Haematology, University College London;

Sir Robert May, Government's Chief Scientific Adiviser;

Professor Sir Peter Morris, Nuffield Professor of Surgery, Oxford University;

Dr Derek Morgan, Reader in Law, Cardiff University;

The Revd Dr John Polkinghorne, Chairman of Advisory Committee on Genetic Testing, member of the Human Genetics Advisory Commission; and

Sir David Weatherall, Honorary Director, Institute of Molecular Medicine, John Radcliffe Hospital.

Memorandum by the Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority

THERAPEUTIC CLONING

1. As requested, here is a short note regarding our jointly published report on *Cloning Issues in Reproduction, Science and Medicine* (December 1998).

2. We held a public consultation exercise during 1998 to explain the issues raised by cloning technology and stimulate wide and informed debate. Our Report reflected the views of those who responded, and made recommendations to Ministers about, *inter alia*, therapeutic cloning.

3. Many respondents to the consultation saw benefit in new therapeutic uses of cell nucleus replacement (CNR) techniques ("therapeutic cloning"), which might be developed to treat serious medical conditions. Some of the therapeutic advances now being developed were never envisaged when the 1990 Act was drafted. Therefore, the Report recommended that the Secretary of State for Health should consider specifying in regulations two further purposes for which the HFEA might issue licences for research, so that potential benefits could clearly be explored: first, for developing methods of therapy for mitochondrial disease; and second, for developing *in vitro* cell-based methods of therapy for diseased or damaged tissues or organs.

4. The most likely objective of a research project involving the use of CNR would be to create a cultured cell line for the purposes of cell or tissue therapy. The eventual clinical use of such procedures would be to provide immunologically compatible tissues for the treatment of degenerative diseases of, for example the heart, liver, kidneys and cerebral tissue, or repair damage to skin or bone. The potential value of such techniques to human medicine is enormous. We noted, however, that these possibilities were speculative, and unlikely to be available for clinical testing for a decade or two, but agreed that it would seem unwise to rule out absolutely any lines of research (not involving reproductive cloning) that might prove of therapeutic value. Our review of the published research at that time led us to conclude that it seemed likely that applications for research projects involving CNR in human oocytes may be received by the HFEA within the next few years.

5. Since therapeutic approaches to disease or tissue damage are not at present included in the purposes for which research can be licensed under the Human Fertilisation and Embryology Act 1990, the making of new regulations would be required to extend the scope of the Act to include these purposes.

6. Another potential future application of CNR would be for the avoidance of mitochondrial diseases. It has been suggested that a woman suffering from such a disease could have a healthy child if the nuclear material from one of her eggs was transferred before fertilisation into a donor egg from which the nuclear material had been removed. Nuclear replacement from one egg to another is not cloning, since after fertilisation the embryo is not identical to the mother, nor to any other embryo. Similarly, because the use of CNR for the avoidance of mitochondrial disease is not at present included in the purposes for which research can be licensed under the HFE Act, the making of new regulations would be required to extend the scope of the Act to include this purpose.

7. We should also point out that there was a significant response, primarily from individuals, rejecting all research using human embryos. However, the Human Fertilisation and Embryology Act permits licensed research on human embryos up to 14 days of development (this stage of development immediately precedes the primitive streak stage at which development of individual embryos is established and cell determination for the future foetus sets in). During the passage of the Bill, an amendment to prohibit the creation of embryos for research was defeated by a large majority in the House of Commons and by a very large majority in the House of Lords. Thus the production of a human embryo by CNR for research purposes could be permitted, provided that the research project was licensed by the HFEA according to the strict criteria that such a licence demands.

8. Since publication of our Report, there has been a number of further developments in the fast moving field of stem cell research and calls by scientists for this research to be permitted. We therefore welcome the establishment by the Government of the Chief Medical Officer's expert advisory group on therapeutic cloning in humans, which has been asked to give this issue further consideration and report quickly.

October 1999

Memorandum by the Department of Health

GENETIC DATABASES

Introduction

1. The Department welcomes the opportunity to contribute to the Select Committee's consideration of an NHS-wide database of patient-specific genetic and clinical information, for use by doctors, clinical researchers and epidemiologists.

2. It has been suggested that such a database has the potential to act as a tool in the development of new or improved methods of achieving better prediction, diagnosis and treatment of disease and in establishing more cost-efficient ways of operating health services. It also raises significant issues about informed consent for use of data and tissues and confidentiality as well as feasibility and cost. All these issues would need to be explored fully with a wide public consultation before any decisions could be made on whether the establishment of an NHS data base was justified. These issues are dealt with in more detail from paragraph 9 onwards.

3. This memorandum also refers briefly to relevant research initiatives currently being led by the Medical Research Council (MRC).

Background

4. The Human Genome Project (due for completion early in the new century) involves the determination of the genetic code of the entire human genome and, combined with appropriate studies, will eventually allow a much better understanding of disease mechanisms. There is therefore significant potential for developments in genetics and genetic technologies to provide new routes to the understanding of complex disorders and the nature of disease. The resources available to support developments in the new science of genomics will be critical.

5. The creation of a system of electronic health records currently under development within the NHS, with standard terminology and rapid, anonymised access will in itself create very important opportunities for research, evaluation, and public health monitoring.

6. Over time, health records will come to include more and more genetic information and diagnostic and predictive tests will become more widely available, and cheaper, in routine care. This information will add to the value of health records for research and evaluation to some degree, but will also increase the importance of a trusted system for protecting confidentiality.

The Current IT Situation in the NHS

7. Information for Health noted that use of patient-based information is at present difficult at both a clinical, operational and health authority level due to the lack of tools presently available to aggregate such data consistent and comparable ways. A range of actions that are to be taken in the NHS were set out with the aim of ensuring that relevant, complete, comparable data is available to support a range of functions, including assessment of performance of the NHS.

8. The NHS Information Authority has a programme of work to extend the development of electronic clinical records across the NHS over the next six years. These records are intended to have core standard elements, thus having the potential to provide the required source data for a national clinical database. Equally, work on classifications and groupings is continuing as part of the Information Authority's work programme, which has the potential to contribute to ways of analysing these clinical records for various purposes. In April 1999, the NHS Executive entered into an agreement with the College of American Pathologists (CAP) to create a new world standard for computerising medical terminology. This is necessary for the effective introduction of electronic health records as outlined in the strategy document *Information for Health.*

Ethical and Legal Considerations

9. In England, personal health information is protected by the common law duty of confidence and, where held on computer in an identifiable form, by the Data Protection Act 1984. The Data Protection Act 1998 comes into force in March 2000 and will cover both computerised information and information held manually in certain types of files. This will include most if not all clinical records. The Data Protection Act 1998, like its predecessor, does not apply to anonymised information. Generally, it requires that:

- the common law of confidentiality be complied with;
- the data subject must not be misled or deceived into giving the data;

— the data subject must be given basic information about who will process the data and for what purpose; and

— in the case of health data, one of the conditions in Schedule 2 and one of the conditions in Schedule 3 of the Data Protection Act must be complied with (see Annex).

10. Under the 1998 Act, data legitimately processed for research or statistical purposes are exempt from certain provisions of the Act as long as the processing neither causes substantial harm or distress to the data subject nor supports measures or decisions in relation to individuals. Such data can be kept indefinitely and are exempt from the subject access rights if the results of the work are not made available in a form from which data subjects can be identified. Use of such data for research, although obtained for other purposes, is not unlawful. However, this does not absolve the data controller from the obligation to give the data subject general information about the intended uses.

11. In addition to compliance with the specific requirements of the data protection legislation, any disclosure of personal health information must also comply with the common law duty of confidence. Any disclosure made with the consent of the individual concerned will meet these requirements. In English law, confidential information can be disclosed *without* the consent of the individual where the public interest in the disclosure exceeds the duty of confidence to the individual. This is a test that must be carried out on a case-by-case basis. In other words, one research project may be sufficiently in the public interest to meet the test but this does not mean all research projects that could be carried out on the same data would meet this test. Even if there is an overriding public interest, where consent *could* be obtained to the release of confidential information, it should be sought. This applies to both identifying and non-identifying information.

12. A recent ruling (*R v Department of Health ex parte Source Informatics Ltd;* Times Law Reports 14 June 1999) confirmed that *anonymised* data derived from confidential patient information continues to be subject to a duty of confidence. This ruling is subject to an appeal due to be heard in late 1999.

13. Questions to be considered in relation to any large scale database of clinical and genetic information would include:

— is the use of personal health information in large scale database justified by the potential research and treatment benefits?

— should data be anonymised?

— should explicit consent from an individual be required before entering information on a database, even if the data are anonymised?

— what safeguards or legal controls should be required to protect confidentiality, consent and use.

14. The use of DNA samples also raises broader ethical questions because of their ability to reveal information about an individual and members of an individual's wider family that they may or may not wish to know. Issues about communication of research results and ensuring that the right "not to know" is respected would need further consideration. Broader issues such as the implications of gene patenting, commercial ownership of personal health information and questions about intellectual property would also need to be investigated further.

Feasibility

15. The feasibility of establishing such a large and integrated resource of medical data has yet to be established. The current rapid development of genomic science means that it is difficult to predict how such a database might be used in the future. This would influence the data definitions and criteria for data entry to ensure amongst other things compatibility of data entered from different sources. The adequacy of existing clinical records to provide such data would need to be investigated.

16. Appropriate security arrangements would be needed to ensure that unauthorised access was prevented. Protective measures would be likely to include access controls to authenticate users, cryptographic techniques to scramble information and safeguard storage and audit logs to record accesses to the information. The exact methods to be adopted would have to be carefully considered both for their effectiveness and for their potential impact on NHS working practices.

17. Resource consequences would depend on the model chosen but are potentially enormous. Techical and security issues combined with the need for long-term maintenance suggest that any national database would be an expensive undertaking.

18. Illustratively, the costs of the Icelandic database of clincial information, which does not yet exist, have been estimated by the Icelandic Ministry of Health and Social Security at 10.5–19.3 billion ISK €129–244 million for a population of 270,000.

Research Issues

19. A number of small and medium-scale databases have been or are being established to study patients with a particular condition or for epidemiological studies. Such collections are funded by various charities, the MRC and by industry. The MRC is currently developing plans for a large prospective cohort to study interactions between genetic and environmental risk factor for disease. The studies will involve consenting patients selected according to specific criteria and will be subject to aprpoval by Research Ethics Committees.

Conclusion

20. In theory, a universal NHS health information and DNA database could be created. In the short-term there are questions about feasibility and affordability. There are also central ethical and legal questions which need to be addressed. Issues around confidentiality, security, control of data, consent to use of health information both prospective and retrospective would all need to be considered. Such issues justify widespread public debate and consultation before decisions are made. It is likely that the new Human Genetic Commission will wish to consider these important issues as a priority when the body convenes for its first meeting early next year.

November 1999

Annex

SCHEDULES TO THE DATA PROTECTION ACT 1998

Section A

Schedule 1—The Data Protection Principles

1. Personal data shall be processed fairly and lawfully, and, in particular, shall not be processed unless—
   (a) at least one of the conditions in Schedule 2 is met, and
   (b) in the case of sensitive personal data at least one of the conditions in Schedule 3 is also met.

2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.

3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.

4. Personal data shall be accurate and, where necessary, kept up to date.

5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.

6. Personal data shall be processed in accordance with the rights of data subjects under this Act.

7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss of destruction of, or damage to, personal data.

8. Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

Part II of Schedule 1 provides a more detailed interpretation of these provisions which should be consulted as appropriate.

Section B

Schedule 2—conditions Relevant for the Purposes of the First Principle: Processing of any Personal Data

1. The data subject has given his consent to the processing.

2. The processing is necessary—
   (a) for the performance of a contract to which the data subject is a party, or
   (b) for the taking of steps at the request of the data subject with a view to entering into a contract.

3. The processing is necessary for compliance with any legal obligation to which the data controller is subject, other than an obligation imposed by contract.

4. The processing is necessary to protect the vital interests of the data subject.

5. The processing is necessary—

(a) for the administration of justice;

(b) for the exercise of any functions conferred on any person by or under any enactment;

(c) for the exercise of any functions of the Crown, a Minister of the Crown or a government department;

(d) for the exercise of any other functions of a public nature exercised in the public interest by any person.

6. (1) The processing is necessary for the purpose of legitimate interests pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject.

(2) The Secretary of State may by order specify particular circumstances in which this condition is, or is not, to be taken to be satisfied.

SECTION C

SCHEDULE 3—CONDITIONS RELEVANT FOR PURPOSES OF THE FIRST PRINCIPLE: PROCESSING OF SENSITIVE PERSONAL DATA

1. The data subject has given his explicit consent to the processing of the personal data.

2. (1) The processing is necessary for the purposes of exercising or performing any right or obligation which is conferred or imposed by law on the data controller in connection with employment.

(2) The Secretary of State may by order—

(a) exclude the application of sub-paragraph (1) in such cases as may be specified, or

(b) provide that, in such cases as may be specified, the condition in sub-paragraph (1) is not to be regarded as satisfied unless such further conditions as may be specified in the order are also satisfied.

3. The processing is necessary—

(a) in order to protect the vital interests of the data subject or another person, in a cases where—

(i) consent cannot be given by or on behalf of the data subject, or,

(ii) the data controller cannot reasonably be expected to obtain the consent of the data subject, or

(b) in order to protect the vital interests of another person, in a case where consent by or on behalf of the data subject has been unreasonably withheld.

4. The processing—

(a) is carried out in the course of its legitimate activities by any body or association which—

(i) is not established or conducted for profit, and

(ii) exists for political, philosophical, religious or trade-union purposes,

(b) is carried out with appropriate safeguards for the rights and freedoms of data subjects,

(c) relates only to individuals who either are members of the body or association or have regular contact with it in connection with its purposes, and

(d) does not involve disclosure of the personal data to a third party without the consent of the data subject.

5. The information contained in the personal data has been made public as a result of steps deliberately taken by the data subject.

6. The processing—

(a) is necessary for the purpose of, or in connection with, any legal proceedings (including prospective legal proceedings),

(b) is necessary for the purpose of obtaining legal advice, or

(c) is otherwise necessary for the purposes of establishing, exercising or defending legal rights.

7. (1) The processing is necessary—

(a) for the administration of justice,

(b) for the exercise of any functions conferred on any person by or under an enactment, or

(c) for the exercise of any functions of the Crown, a Minister of the Crown or a government department.

(2) The Secretary of State may by order—

(a) exclude the application of sub-paragraph (1) in such cases as may be specified, or

(b) provide that, in such cases as may be specified, the condition in sub-paragraph (1) is not to be regarded as satisfied unless such further conditions as may be specified in the order are also satisfied.

8. (1) The processing is necessary for medical purposes and is undertaken by—

(a) a health professional, or

(b) a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional.

(2) In this paragraph "medical purposes" includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services.

9. (1) The processing—

(a) is of sensitive personal data consisting of information as to racial or ethnic origin,

(b) is necessary for the purpose of identifying or keeping under review the existence or absence of equality of opportunity or treatment between persons of different racial or ethnic origins, with a view to enabling such equality to be promoted or maintained, and

(c) is carried out with appropriate safeguards for the rights and freedoms of data subjects.

(2) The Secretary of State may by order specify circumstances in which processing falling within sub-paragraph (1)(a) and (b) is, or is not, to be taken for the purposes of sub-paragraph (1) (c) to be carried out with the appropriate safeguards for the rights and freedoms of data subjects.

10. The personal data are processed in circumstances specified in an order made by the Secretary of State for the purposes of this paragraph.

Memorandum by Dr George Poste, Chief Science and Technology Officer, SmithKline Beecham

POPULATION GENETICS—THE NHS AS A RESEARCH RESOURCE

SUMMARY

— The NHS is an under-utilised research resource in population genetics which could yield large benefits for public health (through enhancing our understanding of disease) and industrial research.

— A public-private sector strategy should be developed to identify and mobilise the appropriate scientific and clinical skills, to build large-scale computational infrastructure and to debate, and address, the ethical, legal and social dimensions relating to the use of clinical information, particularly in the context of privacy and consent issues.

BACKGROUND

1. Healthcare systems across Europe are a substantial but underused research resource. While for some the rising burden of state-funded healthcare is a major political challenge, it is also, potentially, a source from which the information requirements for the new era of medicine could be harvested. Health delivery systems have much to offer in epidemiology, technology assessment, outcomes research and population genetics. There is significant potential for building partnership by sharing data and analyses to enable better health economic decisions to be made and to increase the cost-effectiveness of health services, moving away from the current budgetary debates based on a narrow focus on individual components of healthcare to an integrated perspective of health outcomes and total costs. There are many ways in which industry together with healthcare providers and academic groups can use healthcare information databases. One major immediate opportunity—to delivery quality and equity in healthcare—is in health economics. There is also another major opportunity, described here in more detail, in early research, building on UK strengths in the areas of population genetics.

2. The last five years has seen a revolution in the understanding of disease brought about by the information gained through genetic analysis. Continuing this successful analysis necessitates building population genetics capacity to understand gene-disease associations and to set into their public health context. This requires:

— Suitable genetic technology.

— DNA samples from patients.

— Clinical information on those patients.

3. Major investment by the pharmaceutical industry will help meet the first of these requirements. However, the second and third requirements require a coordinated strategy for public-private partnership.

4. The NHS is generally a substantial, but underused, research resource. It has much to offer in developing new clinical R&D initiatives in population sciences, technology assessment, the coordination of clinical trials and health outcomes research. The UK is uniquely well-positioned to generate valuable epidemiological data: possessing the resource embedded in the NHS of 50 years of family records, ethnic diversity, access to disease (tissue) libraries and excellent clinical and research frameworks.

5. The NHS provides a doorway to probably the largest single source of medical information and well-characterised human biological samples within Europe and has access to substantial populations representing several important ethnic groupings (such as those of Caucasian, Asian and African ancestry). It is also a repository for high level clinical expertise relating to diseases of strategic importance for population health and has access to the large numbers of clinical staff required to evaluate phenotypic data and ascertain DNA.

6. The universality of NHS provision of health care offers access to areas of sample acquisition such as across primary care groupings that is not possible in more fragmented health systems or in the smaller cohorts studied hitherto. The national structure also offers the homogeneity of data acquisition that is essential for large-scale genetic studies. The aquisition of DNA samples and data from routine clinical practice would be preferable to collection from clinical trials—for the following reasons:

— Larger numbers.
— Less selection bias.
— More realistic, community cohort (including matching healthy subjects).
— Opportunity to set unifying standards in research.

This access should be on an anonymous basis to protect the privacy of individual's health data.

7. The likely benefits accruing to the NHS (and the UK as a whole) include:

— Progress in understanding disease at the public health level.
— Provision of new resources to support NHS R&D.
— Stimulating production of novel therapeutics, diagnostics and the better targeting of treatment.
— Attracting inward investment by companies.

8. But, the NHS is a sleeping giant in terms of trying to use this research resource in population genetics. It is important now to begin the informed debate on the options for defining scope and scale—from the extension of current cohort studies, through the expansion of regional NHS links, to a nationwide endeavour. A strategy must be articulated to identify and mobilise the appropriate scientific and clinical skills, to build large-scale computational infrastructure and to debate, and address, the ethical, legal, political and social dimensions relating to the use of clinical information, particularly in the context of medical privacy, use of anonymous data and consent issues. To express this strategy and share value, we require a pre-competitive, public/private consortium, fusing technologies and encompassing NHS R&D capacity, private companies, universities and medical research funders and government. Creation of the health research database transcends both what the NHS is currently doing in information technology (relating mainly to clinical care and governance) and what researchers are building with genomic databases. A consortial approach would generate a new lead for the UK in the biosciences and their application in the delivery of rational medicine.

November 1999

TUESDAY 7 DECEMBER 1999

Present:

Haskel, L.
Jenkin of Roding, L.
Methuen, L.
Perry of Walton, L.
Platt of Writtle, B.
Quirk, L.
Rea, L.
Soulsby of Swaffham Prior, L.
Tombs, L.
Walton of Detchant, L.
Warwick of Undercliffe, B.
Winston, L.
(Chairman)

Examination of Witnesses

JOHN DENHAM, a Member of the House of Commons, Minister of State for Health, YVETTE COOPER, a Member of the House of Commons, Minister for Public Health, and LORD SAINSBURY OF TURVILLE, a Member of the House of Lords, Minister for Science and Innovation, were examined.

DR PAT TROOP, Deputy Chief Medical Officer, Department of Health, was called in and examined.

Chairman

Thank you very much indeed for coming to this Committee. I think it is the first time since I have been on the Select Committee that we have had the privilege of having three ministers from two different departments, and it is very good to see you. We have essentially three blocks of questions and we will try and keep to a fairly vigorous schedule, perhaps allowing maybe 20 minutes for each group. What we generally do in this Committee is, as we go along, to declare our interests. As you might imagine, all of us here will tend to have interests which are involved. It has been pointed out to me that I have a conflict of interest with almost every question that is on the paper, so clearly we will need to declare those as we go.

Clinical Academic Careers

1. I wondered if I might start perhaps with Mr Denham on our first question? This is the vexed issue of clinical academic career prospects. We want to make sure that the Government shares our very considerable concerns about the long-term prospects for clinical academics—the issue of people being pulled out of the very science which develops the National Health Service and which ensures the best standards for young clinicians in training.

(*Mr Denham*) Lord Winston, thank you very much for the opportunity of discussing these issues. Could I take the opportunity of congratulating you on the award of the Royal Society's Michael Faraday Award? I think it was well deserved. I can reassure the Committee that we do recognise the vital role that clinical academics play in training future doctors and, of course, providing NHS services and conducting research. I think that, in its reports, the Committee highlighted a set of concerns that needed to be addressed. I would hope that the series of initiatives that have been set out in the memorandum that we have presented shows that the Government is serious about addressing them. Some of those were issues that fell directly to government to address, such as the concerns about pay parity that were raised in your earlier report. Many of the issues are ones where our role, I think, is to play a leading role in partnership with many of the other organisations that are involved in supporting the role of clinical academics. I would hope that the memorandum shows that not only have we done that but we have identified areas of further work, and progress has already been made.

2. Do you have any problems about the general Calman system of training, whereby there is an allotted structure for research which is within a fairly rigid framework? Do you think that actually contributes to the best form of research training in the NHS?

(*Mr Denham*) When the Calman reforms were first brought into place the initial interpretation of the way in which they would work was seen as restricting the opportunity for doctors in training to undertake academic research. I think the view of the Department is that was a misinterpretation of the position and that is why the supplement to the guide to specialist training was produced, to make clear the opportunities and the flexibilities which did exist within the training system. I understand that last year, for example, the Medical Research Council received 270 applications and was able to award 56 MRC fellowships to doctors in training grades. So I think that we have been done a fair amount to make it clear that there are opportunities to do research. I understand that 9 per cent of specialist registrars are currently out of training undertaking research. Nonetheless, the symposium which was held in October did identify this issue as one that needs further examination. That will be taken forward by the AGMITS Academic and Research sub-group in due course. The short answer is that the problem was not as bad as it was perceived and we have done quite a lot to make sure the opportunities are there. There may well be further issues that we need to look at.

3. You mentioned the MRC training fellowships but, of course, these are very few, as are, indeed, the ones from Wellcome. One of the issues is how you fund that training programme, that research training programme. I do not know whether you feel that it is a very narrow band at the moment?

Chairman *contd.*]

(*Mr Denham*) I certainly recognise that the funding of training places is an issue again that was identified in the seminar which took place in October and needs further examination. I do not think that I am in a position, certainly this morning, to commit myself to further action in that area but I am perfectly willing to acknowledge it as an issue that needs further examination.

Lord Walton of Detchant

4. It is more than seven years since I worked as a clinical academic but I did chair the enquiry conducted by the Select Committee some years ago into research in the NHS in the light of the last Government's reforms. It was this that led to the establishment of the Richards Committee to which you have referred. At that time there were 47 vacant clinical chairs in the United Kingdom; now there are 74, and of those 74 vacant clinical chairs, half have been vacant for more than 12 months. So the position is not at present improving. You make a number of very helpful suggestions in your memorandum. The Calman training programme is one problem but that will be dealt with, I think, when we come to the Academy of Medical Sciences report. Another is the effect of the research assessment exercise. But one that is not referred to in your memorandum is the pressure which is being imposed upon clinical academics to see more and more patients, to increase patient throughput, to reduce waiting lists, all to the detriment of the time available for teaching and research. What are the Government doing about protecting that teaching and research time which should be part of the academic contract?

(*Mr Denham*) There are two key issues that I have highlighted. The first is that Task Group 1, set up jointly with HEFCE following the Committee's previous report and the Richards report, did look directly at the question of the research assessment exercise and have, as you know, made suggestions for changing the next exercise, which should mean that the gap that is perceived between the quality of research and the way in which it was assessed should be addressed. As far as the workload pressures are concerned, what has been done through a number of different fora, including perhaps particularly the Joint Medical Advisory Committee study, is to highlight good practice around the country. I have to say that a constant theme of what I will say this morning is to drive the best practice that does exist across all the medical schools and the universities which have not yet caught up. What is very clear is that, in a number of areas, the particular issues of pressure on the individual are being well addressed by the proper use of job planning and the proper use of appraisal of the individual's workload in the context of a shared approach to all these issues by the university and the NHS. I think it is quite critical that we develop a culture of openness and sharing of approaches between the NHS and the university sector and that is then reflected at the level of the individual, so that the pressures can be recognised, understood and properly managed.

Baroness Warwick of Undercliffe

5. I wonder if I might press the Minister on the question of clinical academic careers, declaring an interest as Chief Executive of the Committee of Vice-Chancellors and Principals? I really want to press you on the urgency of implementing solutions because the lead time for preparing staff for the medical profession means that any steps we take now will still take several years for the benefits of them to flow through. A recent BMA survey, which also highlighted the number of vacant chairs, indicated that the numbers of qualified candidates have been decreasing over a prolonged period and that short-lists are "often shorter than might have been hoped for". We do clearly need new initiatives to attract clinical academic candidates and I wondered whether you could say something about the urgency with which you might be approaching that?

(*Mr Denham*) It is very frustrating that in terms of hard data about vacancies, the length of time posts are left unfilled, the range and quality of candidates coming forward, I have to tell the Committee that we are not much further forward than was the position when the Committee last discussed these matters—and that is despite a considerable amount of effort by AGMETS Academic and Research sub-group that is looking at these issues. A very considerable attempt has been made to work through the various stakeholder organisations to produce the hard information we really need to have to identify the scale of the problem and to tackle it effectively. The reality, I am told, is that the response in terms of the range and quality of information volunteered by the different organisations concerned has not been as good as we would like and so we still do not have a hard picture. I think it is absolutely essential that we redouble our efforts to improve the quality of the data and the monitoring that we have about vacant posts and the difficulty in filling them. That has very much been identified as a priority in the October seminar. It is on their worklist and it will be looked at by the AGMETS sub-group in January. Could I make a plea that anybody—there are a number around this table—who has any influence on the various organisations, encourage their help to produce that data? That will be very useful, because designing an appropriate response must be based on a firm rather than anecdotal or partial survey assessment of the situation. We do need to do that quickly. We are expanding medical training places. The universities that have submitted their bids have told the Joint Implementation Group that they are confident about filling the clinical academic posts that are required. But you are absolutely right: making changes in any workforce, especially in the NHS at specialist level, does take time. I would not like to see us miss the opportunity to do that, not least because we have a much more wide-ranging workforce review under way in the NHS at the moment and we have to make sure that we have taken the complete picture and not a partial picture in that work.

Chairman

6. One of the groups has some of this data, apart from the Royal Colleges, which I know is patchy, is the postgraduate deans. I wonder whether you feel

Chairman *contd.*]

the system of postgraduate deans is an ideal system, given that so many of these postgraduate deans have very little research experience themselves and generally not in the area of specialty that the registrars in that particular region are involved in?

(*Mr Denham*) You have put a question to me that I would like to reflect on. It is not one that I feel that I would like to volunteer a firm opinion upon at this stage in the specific context of clinical academic careers. What I would say, is that the workforce review which we are looking at the moment obviously raises some questions about approaches to training, though has come to no conclusions. It will review the role of all the structures that we have in place at the moment, including the role of the postgraduate deans, and it may reinforce the point I have just made—that, if we identify that we need to take action on clinical academic careers, perhaps we should make sure we are looking at that issue at the same time.

Lord Rea

7. Following on from the discussion we have just been having, could I ask about the implications of the phased increase in medical school intakes, which has been well publicised and is mentioned in paragraph 3 of your memorandum? What are the implications of that for the numbers of clinical academics that are needed to provide for their training? There is already a shortage. Is the accelerated expansion that is necessary to cope with the increased number of students on track?

(*Mr Denham*) We believe that it is. The bids that have been successful suggest that around 140 new clinical academic posts will need to be filled when the implementation is complete, which, of course, is in the period between now and 2005, which is the date at which we expect to achieve the 20 per cent expansion in the number of medical school places. Most of those are concentrated in the six medical schools that have the bulk of the extra places. In the majority of schemes that have been established so far, there have been links with existing institutions to ensure that there is the necessary academic support for those new clinical academic posts. The analysis of the bids that were made suggests that none of the universities is anticipating any difficulty in attracting applications. Some, indeed, reported that they had received significant numbers of applications or recruited significant numbers of clinical academic staff in recent years and had always been able to maintain a good field of high-quality applicants. I recognise that assessment is not identical with other things that have been said this morning, but that is the assessment of the universities that are responsible for carrying out this expansion and obviously their proposals were scrutinised very closely by the Joint Implementation Group, which made recommendations to HEFCE on the allocations.

8. As you suggest, it does not square with the 70-odd vacant clinical chairs. Possibly there are plenty of recruits coming up the system but who have not reached the level to apply for chairs yet. I am just putting that forward as a possible suggestion.

(*Mr Denham*) Certainly, sitting here this morning, I do not have significant concerns about our ability to recruit the clinical academics that we need to carry through the expansion of the programme.

Lord Walton of Detchant

9. The Government may be aware that the BMA is publishing tomorrow a major report on medical student selection[1], which I imagine you will wish to examine carefully. It is relevant to that particular issue. Turning now to the Savill Working Party of the Academy of Medical Sciences, its report is not yet finalised but in draft it suggests that those intent on an academic career should undergo a three-year doctoral programme after they have completed their early graduate training following the pre-registration year, and should then be able to undertake a five-year clinician/scientist post which they hope will have some kind of guarantee in the long term of leading to a major academic career. I think this is a very important and innovative suggestion. Are the Government aware that this is likely to be proposed by the Academy of Medical Sciences?

(*Mr Denham*) I obviously have not seen the report itself. I know that Professor Savill was involved as a participant and speaker in the October symposium on clinical academic careers and that every effort has been made to feed the emerging conclusions of his work into the report of that symposium. All the issues there are going to be looked at by the AGMETS Academic and Research Sub-Group in January, and so we need to take that forward as part of the sub-group's further work.

10. Thank you, because that is when the Savill Report is likely to be approved by the Academy.

(*Mr Denham*) We are keen to make sure that the process is a coherent one and we are not wasting insights and ideas which should be taken into account.

Lord Quirk

11. Clearly in the longer term the supply through the medical schools is going to be terribly important for, for example, recruiting to a doctoral programme such as we have just been talking about. What do you feel about the importance of the intercalated BSc at the undergraduate level as a platform from which to recruit those medical students who might well become the future academics?

(*Mr Denham*) I will take the question, if I may, a little bit more broadly than you posed it. I will write to you on this[2] but, in general, the expansion of medical school places does include a number of innovative approaches for entry into medical education for people who have not done medicine as their first degree. There is a possibility, therefore, that there will be new routes into medicine for people who have already graduated doing another degree for a shorter period of training than would otherwise be

[1] *Selecting our doctors*, British Medical Association, 1999, ISBN 07279 15177.

[2] See supplementary memorandum on page 28.

Lord Quirk *contd.*]

the case, which may in turn produce people who can go on to research degrees.

Lord Walton of Detchant

12. One final brief point, touching on your memorandum: are the Government still considering the issue of distinction awards for academic GPs?

(*Mr Denham*) Yes, we are.

"Therapeutic Cloning"

Chairman: Thank you. We will turn now to the question of therapeutic cloning. It seems rather unfortunate that this whole area of science or medicine, call it what you will, is called therapeutic cloning. I think it has clouded the issue. I find it slightly alarming, if I may say so, being a scientist who is interested in the development of embryology for purposes to improve human health and somebody who is an active researcher in the field, that I am reported by the Genetic Interest Group[3] as saying: Lord Winston condemned the Government's position as "immoral". That is not correct. What I have said was that it was immoral not to use technology which might save or improve human lives, and I hope that everybody understands that. Lord Soulsby?

Lord Soulsby of Swaffham Prior

13. The whole area of genetic aspects of medicine is moving at a very rapid pace and with it a deeper understanding of health and disease. Do the Government share the enormous excitement of experts in this field about the potential benefits of therapeutic cloning and allied procedures, and if so, and I hope so, how do they intend to progress it?

(*Ms Cooper*) Chairman, if I may, I would like to make a few opening remarks in response to that question. First of all, Lord Sainsbury and I will both be answering questions on these issues and I would also like to invite Dr Pat Troop, who is the Deputy Chief Medical Officer, to join in particularly on perhaps some of the medical questions if people want to pursue those further. It is a pleasure to be here in front of the House of Lords Committee on this issue, which I think is extremely important. Out of courtesy to the Committee and to both Houses, I would also like to put on record that I have an uncle living in the States who works in this field. I have raised this with the Permanent Secretary and with others and I am advised by them that there is no conflict of interest, but out of courtesy to the Committee I wanted to let the Committee know that. On behalf of the Department of Health and the Office of Science and Technology, I should like to welcome the opportunity you have given us to contribute on this. Clearly on this issue of research for therapeutic purposes involving the use of cell nuclear replacement or cloning techniques, we have considered the recommendation of the Joint Report of the Human Fertilisation and Embryology Authority and the Human Genetics Advisory Commission. Their recommendation was that consideration should be given to specifying in regulations under the 1990 Act two further purposes for which the use of human embryos in research could be supported. This was, firstly, on mitochondrial disorders and secondly, on diseased and damaged tissues or organs. The Government recognised these recommendations should be considered and certainly the report by these advisory bodies outlines considerable potential benefits from this kind of research. In order to do this and to consider these recommendations, we have asked the Chief Medical Officer to set up an advisory group to look further into the anticipated benefits for human health of such research, also into the potential risks and also into alternative approaches that might be pursued to the same end. The advisory committee's report served to inform public understanding and to gauge public opinion on those issues raised in the consultation document and it has provided a sound basis for further development. The expert group is building on this work, and in particular will address new issues arising as a result of new research and new breakthroughs in embryonic stem cell research which were announced just as the HFEA/HGAC were completing their report. The expert group will be considering the extent of interest in this country in pursuing those areas of research and also the likely timescales for pursuing the research. Once they have assessed those possible benefits, risks and alternatives, the group has also been asked to consider whether they raise any further ethical or social implications beyond those addressed in the HFEA/HGAC report. Finally, if the group decides to recommend a change in the legislation, they will wish to ensure that any changes that they propose are up-to-date with reasonably foreseeable developments in technology. You will be aware, of course, that any proposals to make regulations under the 1990 Act to extend the purposes for which research licences may be issued would need to be laid in draft before Parliament and be approved by resolution of each House before coming into force. So, in deciding whether or not these proposals are acceptable or appropriate in an area that is likely to generate significant controversy, we feel that full evaluation of all the available scientific evidence and also consideration of the ethical issues and public opinion and the options for regulation are fundamental to the debate. Finally, I would also like to reiterate the Government's position on reproductive cloning, which is that it is ethically unacceptable and cannot take place in this country. That was reinforced by the HFEA/HGAC report. I realise it is not the subject of today's questions but I felt it was important to put that on the record again.

14. Thank you very much. I think we are grateful for all the descriptions of the various committees and reports that either have been produced or are in the process of being produced, but it does not come through to me, with due respect, that there is enormous excitement, as my question posed, about the great potential for human health and other health elsewhere too on the use of these technologies and the advancement of them. Obviously it is a hot potato (if

[3] In a Genetic Interest Group policy paper *Therapeutic Use of Human Cloning Technologies,* October 1999.

Lord Soulsby of Swaffham Prior *contd.*]

one might call it that) and one does need to put in place all these considerations, but are the Government excited about the prospects that lie before us with the greater use of these technologies?

(*Ms Cooper*) I think we certainly recognise the huge potential benefits that the experts have advised us could come through as a result of these sorts of developments and this kind of technology. Obviously, from the Government's point of view, we have to take that into account. We also have to examine any further risks and also any alternatives that might be the case and we do have to consider the ethical questions as well. So I think certainly we recognise the advice that we have been given from the HFEA and HGAC about the huge potential benefits, whether it means some of the questions they raise to do with growing tissue to treat degenerative diseases which could be immunologically incompatible, those sorts of things, we do take that very seriously but we do also have to take seriously further issues such as the ethical considerations as well.

Chairman

15. Minister, you have mentioned the ethical considerations repeatedly and I am sure that is absolutely right. Would you not agree that, in view of the 1990 Act already permitting research on human embryos to improve fertility treatment, to improve methods of contraception, to improve our knowledge of genetic disorders and their treatment, that it therefore falls in line for this work to be regarded as being ethical to save lives from serious injury and serious diseases such as cancer?

(*Ms Cooper*) The debate on the 1990 Act is very informative because at that time the House was not able to consider a lot of these issues because the technology had not advanced sufficiently. These were issues and possibilities that the House was not aware of at that time. Obviously, of course, we have to be aware that there will be some people who opposed the 1990 Act and who oppose any further developments in these areas and have very strongly felt ethical views about that, but I think what is also important is that there are a lot of people who will support the 1990 Act but who would feel uncomfortable about any changes to the legislation or any further movement. We have to recognise those considerations as well because there is an ethical question about changing the legislation. Obviously the Houses of Parliament at the time discussed this on a free vote and they decided to place constraints on the kinds of research that could take place. They could have decided that open-ended research could take place in any field but they did decide to place those constraints on it. So I think any possible change to those constraints and to the legislation, because it will involve discussion by the Houses of Parliament—and I think that is right—does need to be very carefully considered. Some people, for example, would describe research around infertility and around congenital diseases as keeping the embryo as both the subject and the purpose of the research, and some people would say, in order to look at other areas and other forms of research, the embryo becomes the subject but not the purpose of the research. So given that people will raise those ethical questions, I think it is extremely important that the Government takes that into account.

16. Would the Government feel that about contraception as well?

(*Ms Cooper*) Obviously in any area where there are ethical questions the Government has to take all these things into consideration. That is one of the reasons that we have asked the Chief Medical Officer's Expert Advisory Group to run through these issues for us and to put them in the public domain.

Lord Haskel

17. I would like to pursue this matter of ethical concern a little further. You may be aware there is a sub-committee of this Committee which is looking at the whole relationship between science and society and the trust that exists between science and society, and we are concerned that this is at a pretty low ebb. I wonder if you could tell us what the Government is going to do to help and educate and inform the public about these obviously ethical concerns because we think that just consulting and taking the view of expert committees is not enough. We feel that probably a lot more needs to be done and I wondered if you could tell us what you are proposing to do?

(*Ms Cooper*) I think it is absolutely right that there needs to be more informed public debate on all these issues. Because of the nature of technology and because these are only now emerging fields, that debate is only just beginning. One of the terms of reference for the recently established Human Genetics Commission will be to develop and implement a strategy to involve and consult the public and other stakeholders, to encourage debate on the development and the use of human genetic technologies and to advise on ways of increasing public knowledge and understanding. So the first point to make is that we hope the Human Genetics Commission will be able to fulfil a role in terms of public education on these important issues, but obviously the process has to go wider than that. In some sense we are talking about improving the basic understanding of scientific concepts, which may involve education in schools but also adult education in the media, to improve scientific literacy generally. You raised the question of trust. We also have to ensure that the regulatory process and the decision-making in all these fields are fully transparent and accountable and people can see exactly what decisions are being taken, on the basis of what information and at what stage. I think that other organisations independent of government can also play a role in this field of promoting education. For example, the Wellcome Trust can play an important role in encouraging public debate but also patient support groups can play an important role in these areas.

Baroness Platt of Writtle

18. Following that up, I was very interested to notice that the CMO's Group are all experts. In our nuclear waste report[4] we said it would be a long time before the public was likely to be able to accept some of these more complex and way-out, in their mind, ideas. So I wonder how you hope to get informed lay opinion which you can take into account? Obviously you would regard that as important and we would, too.

(*Ms Cooper*) Yes. Obviously any consultation process needs to involve that. The CMO's Expert Group has had, I understand, about 100 responses. I am not sure about the position of those responses so I am not sure to what extent those responses to the Expert Group have involved lay people in addition to experts. Certainly that was one of the concerns for the HFEA/HGAC report as well, to take a broad range of opinion, and the Expert Advisory Group will report to ministers in February next year. I do take the point very seriously and the fact that these issues will have to be aired in Parliament if there is to be any change, so there will be a public focus on any debate and politicians, who are obviously generally lay people on these issues, will have to play a role in debating this as well. So I think that, yes, that has to be taken into consideration. We have to make sure that is part of the process as we go on.

(*Lord Sainsbury of Turville*) My Lord Chairman, I think it should be made clear, of course, that the HGAC did have that very particular role in terms of consulting public opinion. It is also, of course, a wider committee, so we have already been, in a sense, through that stage and they have taken those considerations into account. What we are now talking about are quite focused technical issues that we need advice on as part of this process.

19. I accept that, but I feel that it has not really impinged on the public mind yet. Very often, when it does impinge, then the media get hold of it and if one is not careful it is not always very well informed. One wants to make quite sure that one takes account of that opinion before coming to conclusions.

(*Lord Sainsbury of Turville*) Yes. I think, though, that we were very keen that we should not repeat the very good job that the HGAC did for us. Our aim is not to repeat that work but to get some very precise advice which will build on that work and take it forward.

Lord Jenkin of Roding

20. I was very glad to hear Ms Cooper say that there were those who supported the 1990 Act but might have some reservations about this latest proposal. I think I would include myself in that category. I spoke and voted on the Bill in 1990, having been educated by you, my Lord Chairman, on the purposes. Was not the essence of the then Government's handling of the Warnock Report which led to the Act the fact that they allowed it, as it were, to be a subject of quite prolonged public debate? I think there were three years or more between the report coming out and any attempt by the Government to bring the matter before Parliament. That meant that, by the time it reached the House, both Houses, for the first time when there was a vote on the issue of the use of foetuses in research, there were very large parliamentary majorities for the research. As I understand the Government's response on this—and I have a good deal of sympathy with it—it is in order to give time for the public to catch up. In our report that we are still considering on science and society, which I chair, one of the things that we have been aware of is science running well ahead of the public's ability to understand and give assent to what is being done. We really do need to bear that in mind. I heard a very nice phrase over the weekend: "Communication involves ears as well as mouths". I think if that is what the Government are seeking to do and will follow up with the CMO's report, it seems to me that would have some merit. Bearing that in mind, just one final question: is it not just delegated legislation that is necessary? There will not be the full process of parliamentary debate with bills going through committee and report stage. Is that correct?

(*Ms Cooper*) As I understand it, in order to implement the HGAC/HFEA's recommendations would involve regulations, so would involve secondary legislation—if I am incorrect on that, obviously I will write to the Committee to inform you—affirmative regulations which would have to be debated in both Houses.

21. One debate in each House?

(*Ms Cooper*) Yes. However, obviously we still await the Expert Advisory Group's report to see what they advise. So certainly either way there will need to be a debate in both Houses in order even to change the legislation in the way that the HGAC and HFEA suggest. You are certainly right that science cannot run away from public opinion and that the public need to be involved in the debate about all these issues. As I said before, I think that we are still at an early stage of that debate because a lot of people are not aware of the nature of these new technologies, of the potential benefits, of whether there are any alternatives. All those things have not been fully aired and been discussed publicly and I think they need to be. In part, I would come back to my answer to Lord Haskel's question about the role of the HGC in actually promoting that debate. I think it would be wrong for us simply to say we just sit back and wait for the debate to percolate without actually trying to encourage debate about these issues, and that is what I believe the HGC should be doing.

22. May I follow this up? When the CMO's Committee looks at this question, as the Lord Chairman raised right at the beginning, the phrase "therapeutic cloning" is really open to wide misinterpretation; and the phrase that you use in the Department of "cell nuclear replacement" seems to me to be a much more accurate description. One remembers that when nuclear magnetic resonance first came in there was a terror about it because of the word "nuclear". It then became MRI and is now widely accepted as a perfectly normal diagnostic or treatment facility within the Health Service. Names actually are very important to the public.

(*Ms Cooper*) Yes. I certainly hope the Expert Advisory Group will look at all those things.

[4] *Management of Nuclear Waste*, 3rd Report 1998-99, HL Paper 41.

Lord Walton of Detchant

23. I wholly agree, of course, with Lord Jenkin that the word "cloning" should never have been used in this context because it is not cloning as most people understand the term. I also should point out that, when the 1990 Act was passed after the Warnock Report, it actually was introduced to regulate research which had already begun. The idea of these procedures we are now considering is to allow under that Act, by regulation, procedures which have not yet been carried out in this country. It is, however, important to recognise that the difference in an ethical sense seems to me to be minimal. After all, under the 1990 Act it is possible to study embryos within the first 14 days to determine whether or not the gene responsible for a disease such as cystic fibrosis or muscular dystrophy is present and to implant only those embryos which are free from those genetic disorders. When I was personally involved in research into neuromuscular disease over many years I saw many patients with mitochondrial disease. These disorders are rare but they produce devastating evidence of brain damage, often epilepsy, paralysis and eventually progressive muscular weakness leading to a fatal conclusion. This kind of research would allow a woman's nucleus from one of her donated ova to be introduced into another cell from a donated ovum from another woman in order to allow her to have normal mitochondria. Do not forget that particular embryo so created would have 99 per cent of her DNA because only one per cent of the DNA is carried in the mitochondria responsible for these devastating diseases. Frankly, I do not see that is in principle ethically a very different situation from that relating to research carried out under the existing Act. It could prevent a number of very damaging and fatal diseases.

(*Ms Cooper*) Certainly I recognise that point of view. The Government have not taken a position on these ethical issues at this stage. That is one of the things where we want the Expert Advisory Group to explore some of these issues in more detail. What I want to point out by raising these ethical considerations is that I think they are complex. Whilst I certainly respect Lord Walton's point of view on this, obviously there are other points of view as well. Some people argue that, yes, the ethical step is very small; other people argue that the ethical step is very big. Some people argue we should not take that step at all; some people think it is a difficult step but on balance, given the other ethical considerations, we should take it. I think all these are important points of view and need to be considered and need to be fully publicly debated. That is not in the slightest to denigrate the other ethical arguments that are in place. It is simply to say that I think these issues are very complex and the role of Government obviously is to take a balanced view, having considered these carefully.

Lord Tombs

24. It does seem to be the case that the sheer complexity of some of the issues we are discussing today and the unfamiliar and far-reaching effects that they promise gives the opportunity for single-interest groups to develop very focused arguments, not necessarily always balanced, which are attractive to the press. The thing that has been exercising us in another forum is how to try to offset that. One needs a champion for this, a voice of interpretation somewhere. Should that rest with the researchers or is there a case for an independent body? Clearly the regulatory bodies like the HFEA cannot do that, they have to weigh evidence, but there does seem to be a lack of focused response to many of the international centres of concern. Do you have any ideas on that?

(*Ms Cooper*) Yes. I think this needs to be a matter for those who feel strongly about any of these issues to come forward and champion them if they feel that their views are not being heard properly or the benefits of the new technologies or the complications involved, whatever it might be, are not fully being heard. I think it is a matter for them to become champions if that is something that they feel is important. As you said, I think it would obviously be inappropriate for the regulatory bodies to do so and I think in general it would be inappropriate for government bodies to take a one-sided view of any of these issues. Obviously the role of Government has to be to take a balanced view, weighing all the issues in consideration, and also very much to make clear to the public that the role of Government is to provide objective information and to make balanced judgments rather than to be particularly promoting one side of the argument rather than another. Especially given the earlier discussion about public trust in these areas, that is something that the Government have to keep in mind at all times.

25. I agree with much of that. The problem is that the people promoting research or engaged in the research are necessarily involved in the narrow aspects of that research and not necessarily the ethical ones or the public apprehension ones. Also, they may be perceived as self-interested, and so it may be there is a case for some external body that can co-ordinate these views. The Royal Society have taken views in some instances and there may be room for expansion there of that type of activity perhaps?

(*Ms Cooper*) To reiterate, I think that would be a matter for them. It would be wrong for the Government to encourage or comment on a particular side of it like that. I am aware that in other countries other groups, perhaps patient support groups, play a different role or have been more articulate on some of these issues in terms of contributing to the debate, but again I think it is not a proper role for the Government to do that.

26. It is a proper role for Government to be concerned about it?

(*Ms Cooper*) Certainly.

27. And to be searching for a solution?

(*Ms Cooper*) Certainly a proper role for Government to promote informed debate and provide information and to encourage providing that information.

28. And to be concerned about the present existence of somewhat biased presentation?

(*Ms Cooper*) Yes. I think again that is a matter for people who feel that their voices are not being heard to decide if they want to come forward and become champions, as you say.

Lord Walton of Detchant

29. While appreciating all the anxieties and the need for extensive consultation, which all of us agree with, has the Government a formal timetable? When do they expect the CMO's report? One reason for anxiety is that there are some dedicated research workers who are actually contemplating moving overseas in order to carry out this particular programme of research.

(*Ms Cooper*) The timescale for the CMO's Expert Advisory Group is that we expect them to report to ministers in February 2000. They have, I understand, met three times now and taken 100 responses and are currently considering those responses. One of the issues that they were asked to look at was the timescale for potential research in this field and what the particular timescale would be, what the demand was to take forward research in any of these areas. Perhaps I could ask Dr Troop to make a few further points about the nature of the research and the timescale?

(*Dr Troop*) Yes. My understanding is that there is only one licence from the HFEA on stem cell research in this country and that is going ahead at the moment. The feedback from the Committee is that they have had discussions with many of the scientists and they feel at the moment that the timescale of the Committee will not hold up their research. They are able to do sufficient basic research. It is being able to take that research further.

Baroness Warwick of Undercliffe

30. Just very quickly to follow up the point, we all seem to be recognising the difficulties associated with the public understanding of science. It seems to me that in one or two of your answers you also seemed to be implying that there was a problem of scientists understanding the public. Could you say something about that and also about the role of scientists in presenting clear and authoritative information without the so-called political spin that might be needed in order to respond in the way you seem to be suggesting?

(*Ms Cooper*) Yes, scientists have a role in providing proper information publicly, and the Chairman is probably one of the experts in this field in terms of communicating to the public on scientific issues. It is worth saying that I think from the public point of view scientists probably have more credibility than politicians in talking about a lot of these issues and communicating about them. I think that the debate certainly needs to be a two-way one and that it needs to involve everybody, not simply the experts working in the field who are particularly involved in the research but also people right across the piece, people who come new to the research for the first time, who do not know very much about it and who might be concerned about some of the ethical considerations or about the medical research itself. So I think, yes, there has to be a two-way process, and, yes, I think the role of scientists is crucial in terms of being part of the communication and not simply having politicians as the intermediaries between the scientists and the public. Again, hopefully, that is the role that the HGC will be able to play to improve matters in that area.

(*Lord Sainsbury of Turville*) I do think it is very important that scientists do talk about the benefits and the potential benefits of their work in this area, so that they are seen to be concerned very deeply with these issues and not simply about the scientific excitement and interest. Everything points to this being what people are very much interested in: what are the benefits of this which can be set against the risks and the problems? So I think that it is very important that scientists do talk about the benefits of their work as well.

Possible NHS-wide Genetic Database

Chairman: I was just about to offer Lord Sainsbury the last word and he has provided it, thank you. We had better move on to genetic databases. There has been a growing interest in this, I suppose, since the Iceland proposal. Lord Soulsby, would you like to kick off?

Lord Soulsby of Swaffham Prior

31. The witnesses will be aware that George Poste, who until recently was at SmithKline Beecham, has provided us with a very upbeat assessment of the potential for an NHS-wide genetic database. He sees the National Health Service as a robust repository of the important genetic information about health and disease in the country and the regional problems and so on—quite unlike any other country in the world. In contrast to the marked upbeat assessment that Poste does in this document, the Department memorandum is more or less agnostic about it. Do the Government see the significant potential benefit weighed against the obvious and undoubted practical problems of getting this? The way forward, we would believe, is to take up Poste's suggested assessment and use this essential information to the benefit of the national health in its broadest sense?

(*Lord Sainsbury of Turville*) Perhaps I can deal with this question and can I also welcome this opportunity to talk to the Committee about this? I think it might be helpful at the beginning of this to put George Poste's proposal in the context of what is already happening in this field and the Government's action that it is already taking. As I am sure you know, the Government have already invested a significant amount of money in genetics. In the comprehensive spending review, the Medical Research Council and the Biotechnology and Biological Research Council both received increased allocations for biomolecular and biomedical research into the human genome. This included £12 million to the MRC to develop a database of genetic and clinical information designed to look at the interaction between genetic and environmental factors in disease. It is very important to make the point that participation in this database will be entirely voluntary. The MRC is also working closely with the researchers to identify what needs to be included in this database and it is also taking careful steps to address the social and ethical issues raised. I believe this is a first step on which we can build in the future. Currently, discussions are taking place between the MRC and other funders about establishing a major clinical and genetic database with a cohort of 500,000 individuals. Participation in

Lord Soulsby of Swaffham Prior *contd.*]

this will also be, again I make the point, entirely voluntary. For that database, electronic access to national health records would be needed to assure efficient and cost-effective follow-up. Then we are considering George Poste's proposal. I do not think he is, in fact, basing his memorandum on suggesting that we immediately go to a nationwide database, although at some stage we would need to consider that after we have gained the sort of experience we are gaining on limited databases. That would raise very significantly greater issues in terms of both the ethical and the social questions. Of course, it would also raise huge cost implications. If you base it on the Iceland situation, you would be talking about huge costs. It would be a very real question as to whether the additional benefits you got from that made those costs applicable to the sorts of databases we are talking about at the moment.

Lord Rea

32. Lord Soulsby said he thought that the Government's memorandum was perhaps agnostic on the issue. When I read it I thought it tended more towards atheism! I felt it was rather a negative view and did not give adequate space to the benefits that might possibly ensue. Do the Government consider that, if further work does show that the proposal might be worthwhile, that the various problems to do with the security of the data could be overcome? Do you think that there is a positive place for this suggestion?

(*Lord Sainsbury of Turville*) As I hope I have made clear, we are taking action, which is clearly based on the assumption that there will be substantial benefits that will come from this kind of research. But, equally, the ethical and the legal issues are very real ones. At each of the stages of development that I have been talking about in the development of databases, we will need to address those issues in a process which is open public consultation, which involves giving people information and discussion of the risks and benefits, so that we do have full public involvement as we go forward. The issues do change and become much more difficult as you go towards a national database as opposed to purely voluntary ones on a limited scale.

33. George Poste's memorandum talks a lot about the need for the data to be anonymised so that patient confidentiality is not breached. In large-scale epidemiological studies this is surely possible. It may, however, be difficult to see how you could get the information from particular patients and yet conceal their identity. Do you see ways in which this problem can be overcome?

(*Lord Sainsbury of Turville*) I think at this point all one could say is that there are very substantial issues, and a whole range of problems, which would need to be sorted out. I think the biggest one is simply that it would no longer be on a voluntary basis and people have strong feelings about that. There are also all sorts of other issues about the use of information and so on, patenting on the basis of it, which would need to be considered. We will need to do that as we go forward.

Lord Soulsby of Swaffham Prior

34. If I can come back for a moment on the issue of eventual cost? I think George Poste envisaged that the private sector would come into this in a very substantial way. Of course, the genetic database would be of tremendous importance to pharmaceutical companies in their development of new products and the rest. So where do you see the private sector cutting in on this, (or maybe it is there already, I do not know), but possibly somewhere down the road do you see a strong role for the private sector to contribute?

(*Lord Sainsbury of Turville*) I think it is very important, as we develop these databases, that very clear consideration is given to the needs of the pharmaceutical industry in terms of research and developing new drugs to meet diseases. That must be a fundamental part of it. We need to take very strong account of that in designing them. I think equally it is probably extremely important that these are seen to be public databases, under public control, and there are not questions, therefore, about commercial considerations dominating what takes place. The specific question about what contribution is made financially is one we still have to tackle, but certainly it is important that their views are taken account of, as to what information would be useful for drug use.

Lord Haskel

35. Just a very simple practical point, do you think that the information technology is actually going to be in place to carry out George Poste's suggestion?

(*Lord Sainsbury of Turville*) I think that is probably one for Yvette Cooper to talk about from the National Health Service perspective. I do not think, at this stage, this is an issue. Clearly, in terms of the wider world and what is happening on information systems, it would be important in what is designed, that if it was potentially wanted then it could be done, even though at this stage we do not have any plans for it. So, as always with information systems, it is important that they are designed with flexibility for the future, even if at this point there are no specific ideas about what that would be.

(*Ms Cooper*) Just to add to that, the NHS Information Technology Strategy is involved in introducing electronic health records between now and 2005. As we develop that technology and computerise whole swathes of the NHS, this has to be with future developments in mind: to make sure that we are not closing off any potential future developments in technology, should they become beneficial in the future, with the design of the technology we adopt today. As far as possible, that forward looking approach is taken into account. It is worth saying that the kind of proposal from George Poste of SmithKline Beecham, of an NHS-wide database, is hugely ambitious in terms of the technology; in terms of linking hospitals, Gps, and that kind of follow through. In addition to the ethical and legal considerations that would all need to be satisfied, there is the further question about how much additional benefits it would create on top of the kind of sample approach that MRC is exploring, at the moment, which obviously has the benefits of

Lord Haskel *contd.*]

being a voluntary programme as well. So obviously there are resource implications and technical feasibility questions, none of which are in any way likely to be resolved in the near future.

Lord Methuen

36. I think most of the points have been answered but I see the present IT systems in the National Health Service as being essentially a series of islands in terms of the Gps and the hospitals. Obviously you need to take this much more forward with far greater integrated systems. Do you think your present strategy will limit that?

(*Ms Cooper*) I will make a broad point and Pat Troop will want to add something to that. Obviously the aim is not to constrain future developments. The aim is to have systems which will allow future developments to take place, (whatever we may decide they may be in the future)—to have a system which allows us to take advantage of future developments. Obviously, with the way that technology moves and the pace of change, you can never guarantee that you will be able to do something with your technology in ten years' time that you were able to foresee today as the right thing to do.

(*Dr Troop*) The programme is first to ensure that hospital records are wholly computerised, and general practitioner records are computerised, but it is also to develop the links between them so that they will not have islands. Therefore, during the course of the next six years, there should be the links between the Gps and the hospitals to get the laboratory tests: for example, out-patients' appointments, waiting lists, and so on. That is part of the programme over the next six years, so that we will not have the situation you described.

Baroness Platt of Writtle

37. In our report on resistance to antibiotics[5] we were struck by the incompatibility of different IT systems within the National Health Service. All right, I am glad to hear that there is a programme until 2005, but are you ensuring that, in that period, people will not be putting in incompatible systems? It seemed to us that it was very urgent that they should be compatible and able to communicate through the IT system with the various islands you are talking about.

(*Mr Denham*) That is my area. Yes, the answer is that we are determined to make sure that the systems are compatible. The requirements of the system have been clearly set out in a number of documents over the last couple of years. Each part of the health service has to have local implementation strategy, setting out the period of years up to 2005, the strategy to be achieved in that local area. There are some key projects nationally, ensuring that Gps are linked into the NHS net, through which we can be sure we either have the same or entirely compatible systems in place. So we do recognise the need to avoid the mistakes of the 1980s, where particularly systems were built like a series of chimneys which could then not talk to each other, even within the same area from one part of the health service to another.

Lord Jenkin of Roding

38. When the Select Committee went to SmithKline Beecham in Harlow earlier this year, I found myself hugely excited by George Poste's proposal, when he spelt out how increasingly treatments—and, particularly, more complex drug treatments—have different effects on different people with different genetic make-ups. This is a science which is comparatively young but the potentiality of targeting treatments to people who have particular genetic make-ups in their persons seems to me to be enormously important and have huge potential in it for saving money and for increasing human health and happiness. I just wonder whether, as I said at the time, this is an appropriate subject for a select committee inquiry? There was a sense around the table that it might be. Having heard Ministers and your 2005 timescale, and what Lord Sainsbury said about the nature of the work, accepting all the difficulties of confidentiality and patient consent and so on, would a study over the next 12 months be premature? Should we wait or is this something that you feel that, with the considerable expertise that sits round this table, this might help the Government forward?

(*Lord Sainsbury of Turville*) May I say, first of all, I do not think there is any question that we do not share that vision. What the sequencing of the human genome will lead to, above all else, is a radical change in medicine. This will mean that, to a much greater extent, treatment is targeted at individuals to take account of their genetic make-up. That is going to be a major change. As you said, in terms of human happiness and welfare, this will be a very significant and important change. It is also clear that this work needs to be underpinned by the kind of databases that we are talking about. I do not think, in that sense, that we differ at all from George Poste's view of this. The question is, what is the extent of those databases, which really gives you the benefits without going into astronomical costs? Clearly, to have a nation-wide genetic database, the costs of that are huge. The question is, how do you get that information in the most effective way, taking account of all these ethical and social considerations, without overwhelming costs? That is the issue, not the issue about the obvious benefits which will come from this. I think that this is a subject where a lot of thinking is taking place at the moment. I know that the Foresight Programme, one of which is looking at health care, will be focusing on this very particular issue. So I would like to comment that this is the right moment but certainly the widest public discussion of this would be helpful.

(*Mr Denham*) If I could add a point briefly to Lord Jenkin, which is simply to say that, whilst we have been discussing this morning a particular proposal for a database, of course the National Health Service is moving ahead in the areas of genetic testing in the system; regional specialised commissioning groups, which are responsible for ensuring that we have the

[5] *Resistance to antibiotics and other antimicrobial agents,* 7th Report 1997-98, HL Paper 81.

Lord Jenkin of Roding *contd.*]

right concentration of new specialist services in the National Health Service. Their priorities for the coming year will be ensuring the appropriate provision of specialist genetic testing in those areas where it is already directly applicable to medical science at the moment. There are issues to be dealt with in the future but this is also happening in very important areas in the health service already.

Lord Jenkin of Roding: But, as Lord Sainsbury recognised, in the area of what Poste calls "population genetics"—this is what we are talking about in this one—this takes us outside the obviously important things which Mr Denham has been speaking about.

NHS Research and Development Strategy

Chairman

39. I am conscious of the pressures on your time. We do have some more questions on NHS R&D. Would you like to answer that or do you feel that the time is too short?

(*Mr Denham*) Please go ahead, my Lord Chairman.

Lord Perry of Walton

40. I was a member of the Committee which reported in 1988[6], and which led to the establishment of the R&D strategy in the NHS. We have heard rumours that this arrangement may be struggling, possibly because of inter-trust competition in some areas. Can you assure us that the original vision is still being realised?

(*Ms Cooper*) On the issue of the inter-trust competition, obviously that was a feature of the internal market, which has been abolished by the Health Act of 1999. The internal market has been replaced by integrated care, involving greater collaboration between commissioners and providers of health, as well as social care. Obviously, R&D strategy in future needs to be seen in that context, which is a changed context. The R&D is an important part of the modernisation programme in that respect. What we need to do is to make sure that all of the clinical and managerial and policy decisions made in this field are evidence based. The Central Research and Development Committee of the NHS has just completed a review of its priorities for the NHS R&D investment, and the operation of its funding system in the future, the outcome of which will be announced. That will be in the new year. This is in the context of a situation where we expect to see far more collaboration and far more partnership working between sections of the NHS right across the country, as one way of getting round the problem that you have raised.

Lord Perry of Walton: You can, in fact, reassure us that it is going to go ahead?

Lord Walton of Detchant

41. And have you reached the 1.5 per cent target of NHS expenditure to be spent on R&D, which was the original proposal?

(*Ms Cooper*) Not being responsible for the R&D area I cannot answer that but I am sure we can write to the Committee on that point[7].

Chairman

42. One of the issues—I declare an interest in being a R&D director—I notice that there are some parts of London where you have one medical school but several trusts, and there are problems very often because of the commonalities in research but different health care issues. Do you think there are ways round this in the management of the NHS?

(*Mr Denham*) Picking up what Yvette Cooper has already said, the Strategic Review of the way the research and development levy operates will help to address these issues. The first has been considering a number of research priority areas and investments needed in them. What follows from that is that they have been looking at how we might improve the funding systems, so that we do target funding more effectively and get better value for money from our research effort. That obviously has to include the institutional arrangements through which that is actually delivered on the ground. We have been doing this work and the Ministers hope to report on the conclusions they have reached, having looked at that report, in the new year.

Lord Jenkin of Roding

43. May I ask if Yvette Cooper has recognised, what she was describing as the collaboration between trusts and authorities and between trusts and trusts, that this was already happening effectively in some areas well before the change in the new Bill? I particularly should declare an interest as a former Chairman of the Forest Health Care Trust where we were doing just that.

(*Ms Cooper*) I am extremely glad to hear that this kind of collaboration is going on. Certainly, I know there are other parts of the country where effective collaboration is not happening in the way it should be, but it is reassuring to know that it has been going on in some areas.

Chairman: I think there is a widespread feeling that it has not been a universal phenomenon, unfortunately. Ministers and Dr Troop, you have been colossally generous with your time. We are very grateful to you for coming. Thank you very much indeed.

[6] *Priorities in Medical Research,* 3rd Report 1987-88, HL Paper 54.

[7] See supplementary memorandum on page 28.

Supplementary memorandum by John Denham MP

When I appeared before the Committee on 7 December I was asked about the importance of the intercalated degrees for medical students as a platform from which to recruit future clinical academics[1]. I promise to write on this issue.

I understand that most medical schools offer students the opportunity to take an extra year in the middle of the course to study for an intercalated honours degree. Medical schools' policies on intercalation vary: in some schools intercalation is compulsory; some schools actively encourage intercalation; some others limit the number of students who are allowed to intercalate.

At last October's symposium on careers in clinical academic medicine it was suggested that there was a need to identify and nurture potential future clinical academics at an early stage including during the undergraduate course. The symposium noted that intercalated degrees and the new accelerated courses for graduate entrants had an important part to play in this process. The Council of Heads of Medical Schools will be giving this matter further consideration as part of the follow up on the symposium.

17 January 2000

Supplementary memorandum[2] by Yvette Cooper MP

NHS R&D FUNDING: 1.5 PER CENT TARGET

BACKGROUND

1. The previous administration established a target for expenditure on R&D of 1.5 per cent of the NHS Budget. This was before the introduction of the current NHS funding system in which the NHS Trusts were asked to declare how much they spent on or in association with R&D. This target was based on comparisons with the private sector which indicated that a typical proportion for R&D expenditure was between 1 per cent and 2 per cent of total budget[3].

2. In 1993, it was not known exactly how much was being spent on R&D in the NHS Estimates in 1995 suggested 1.2 per cent of total NHS resources were associated with R&D and this estimate was quoted in a Government response to a House of Lords Select Committee report. At that time, the Government stood by the target of 1.5 per cent set out in *Research for Health*[4].

3. However, it was also acknowledged, in evidence given to the Select Committee[5], that as information systems on NHS R&D funding improved we should not be enslaved by the 1.5 per cent target.

4. In the last three years, the NHS R&D Levy has represented the following percentage of totals for NHS resources:

	1	2*	3*	4	5
	NHS R&D Levy £m cash	Total Hospital & Community Health Services £m cash	Total Health £m cash	Column 1 as a percentage of column 2	Column 1 as a percentage of column 3
1997–98	426	30,025	34,664	1.4	1.2
1998–99	426	32,161	36,860	1.3	1.1
1999–2000	435	34,512	39,703	1.3	1.1

* Figures from *Departmental Report on the Government's expenditure Plans for 1999–2000*

DISCUSSION

5. The 1995 government response to the Select Committee said that one of the principles of the NHS R&D Levy was that R&D funding should remain on the historical pattern until improved information systems were in place. These information systems would cover R&D activity, costs, outputs and quality[6]. The NHS made its first annual reports on allocations from the NHS R&D Levy in 1999. The electronic National Research

[1] Q11 on page 19.
[2] Further to Q41 on page 27.
[3] See *Research for Health 1993,* page 6.
[4] See *Research for Health,* Cm 2984 1995, paragraph 56.
[5] See *Medical Research and the NHS Reforms,* Evidence 1994–95, HL Paper 12-1.
[6] See *Research for Health,* Cm 2984 1995, paragraph 57.

Register containing 50,000 records of research activities in the NHS (including some 20,000 current) was also launched in 1999.

6. 1.5 per cent of total health spending in 1999–2000 was £596 million. Increasing R&D expenditure to that level would have meant reallocating £160 million which would otherwise be spent on patient care.

Recent Developments

7. A strategic review of NHS R&D funding was concluded in October 1999. Recommendations are currently under consideration by Ministers. The review made a number of recommendations for further improving information on R&D activity.

Current Policy on the Level of NHS R&D Funding

8. In these circumstances, we question the need for a financial target. We should work to ensure research in the NHS is of consistently high quality, and that the choice of research topics responds appropriately to the priorities and needs of the NHS.

9. The Government's aim is to ensure that there are enough resources to meet the Health Service's needs for research and its commitment to provide the NHS base for the national science effort. It takes account of the contributions of other funders of R&D in the NHS, including the research councils and medical research charities; as well as of the universities that provide the academic base for health research.

10. The level of funding through the NHS R&D Levy is kept under review to achieve these aims.

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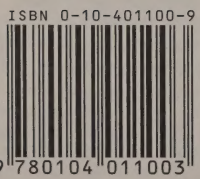

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